Impella CP®

Circulatory Support System

INSTRUCTIONS FOR USE & CLINICAL REFERENCE MANUAL

(United States only)

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IMPORTANT NOTICE: Read this entire manual before using the Automated Impella® Controller and Impella CP® Circulatory Support System (Impella CP® System). The Impella CP® System is to be used only in accordance with this manual.

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IMPELLA CP®
INSTRUCTIONS FOR USE
& CLINICAL REFERENCE MANUAL

(UNITED STATES ONLY)

Rx Only

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INTRODUCTION

PURPOSE OF MANUAL

This Instructions for Use & Clinical Reference Manual is designed for healthcare professionals. It contains clinical and technical information to guide healthcare professionals in their use of the Impella CP® Catheter with the Automated Impella® Controller. The Impella® System performs life-sustaining functions. To use the system you must understand and follow these instructions. The Impella® System may be used only for its intended purpose.

MANUAL OVERVIEW

This manual provides instructions for use of the Impella CP® Catheter with the Automated Impella® Controller. The following summarizes the contents of each section of the manual.

- **Section 1: Warnings and Cautions** discusses the warnings and cautions pertaining to the use of the Impella® Catheter with the Automated Impella® Controller.
- **Section 2: Indications, Contraindications, and Potential Adverse Events** discusses indications for use of the Impella® Catheter with the Automated Impella® Controller, contraindications, and potential adverse events that may be associated with the use of the system.
- **Section 3: The Impella® Catheter and Automated Impella® Controller** provides an overview of the system and describes its major components and features.
- **Section 4: Using the Automated Impella® Controller** describes the controls and various screen types on the Automated Impella® Controller.
- **Section 5: Using the Automated Impella® Controller with the Impella® Catheter** provides the procedures for using the Impella® System.
- **Section 6: Patient Management Topics** provides key information on various topics related to management of patients with the Impella® Catheter and Automated Impella® Controller.
- **Section 7: Automated Impella® Controller Alarms** provides a listing of Automated Impella® Controller alarms as well as information on what to do to resolve them.
- **Section 8: General System Information** contains information including definitions for key terms that appear in the manual, descriptions of the abbreviations and symbols that appear on Impella® Catheter and Automated Impella® Controller components and packaging, technical information pertaining to the Impella® Catheter and Automated Impella® Controller, and instructions on cleaning and storing system components as well as returning components to Abiomed.
- **Appendices** at the end of the manual provide supplemental information about topics including the Impella® Limited Service Warranty; Abiomed-approved introducers; the Automated Impella® Controller menu structure; and axillary insertion technique.

1 WARNINGS AND CAUTIONS

WARNINGS 1.1

CAUTIONS 1.3

WARNINGS

	Use of the Impella® System by trained and experienced practitioners has been associated with improved outcomes. Consequently, the first use of Impella® should be preceded by the completion of a contemporary Abiomed Impella® training program and include on-site proctoring during the first use by Abiomed clinical support personnel certified in the use of Impella®.
	The safety and effectiveness of this device has not been established for use in providing partial or full support of the blood circulation for periods of greater than 6 hours, or for providing prophylactic hemodynamic support, for example, in patients with stable hemodynamics during percutaneous interventional procedures of high risk coronary artery lesions and/or anatomy.
	Fluoroscopy is required to guide placement of the Impella® Catheter. The small placement guidewire must be reliably observed at all times.
	Be sure that the stopcock on the peel-away introducer or repositioning sheath is always kept in the closed position. Significant bleed back can result if the stopcock is open.
	Avoid manual compression of the inlet and outlet areas of the cannula assembly.
	The sterile components of the Impella® System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.
	Do ***NOT*** resterilize or reuse the Impella® Catheter. It is a disposable device and is intended for single use only. Reuse, reprocessing, or resterilization may compromise the structural integrity of the catheter and/or lead to catheter failure which, in turn, may result in patient injury, illness, or death.
	Retrograde flow will occur across the aortic valve if the Impella® Catheter is set at P-level P-0.
	To prevent malfunction of the locking mechanism of the peel-away introducer, do ***NOT*** hold the hemostatic valve while inserting into the artery.
	To prevent failure of the peel-away introducer, remove the peel-away introducer prior to transport when activated clotting time (ACT) is less than 150 seconds.
	Do ***NOT*** use saline in the purge system.
	Do ***NOT*** use an Impella® System if any part of the system is damaged.
	To prevent the risk of explosion, do ***NOT*** operate the Impella® System near flammable anesthetics.
	If at any time during the course of support with the Impella® Catheter, the Automated Impella® Controller alarms "Purge Pressure Low" or "Purge System Open," follow the instructions presented in section 5 of this manual.
	Do ***NOT*** subject a patient who has been implanted with an Impella® Catheter to magnetic resonance imaging (MRI). The strong magnetic energy produced by an MRI machine may cause the Impella® System components to stop working, and result in injuries to the patient. An MRI may also damage the electronics of the Impella® System.

Warnings

Warnings alert you to situations that can cause death or serious injury. The red symbol ⚠ appears before warning messages.

	Cardiopulmonary support (CPR) should be initiated immediately per hospital protocol if indicated for any patient supported by the Impella® Catheter. When initiating CPR, reduce the Impella® Catheter flow rate. When cardiac function has been restored, return flow rate to the previous level and assess placement signals on the controller.
	During defibrillation, do ***NOT*** touch the Impella® Catheter, cables, or Automated Impella® Controller.
	Power the Automated Impella® Controller using its internal battery if the integrity of the protective earth conductor is questionable.
	Lithium-ion battery replacement by inadequately trained personnel could result in excessive temperatures, fire, or explosion. Only technicians authorized by Abiomed should remove or change the battery.
	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	No modification of this equipment is allowed.
	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in section 8 of this manual.
	During transport, the Automated Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Automated Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Automated Impella® Controller is no longer exposed to the disturbance.
	Portable and mobile RF communications equipment can affect medical electrical equipment.
	The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
	Use of cables, other than those sold by Abiomed, may result in increased emissions or decreased immunity of the Automated Impella® Controller.
	The Automated Impella® Controller uses RFID (radio frequency identification) to identify and communicate with the purge cassette. Other equipment may interfere with the Automated Impella® Controller even if that other equipment complies with CISPR emission requirements.
	Infusion through the sideport of the introducer can be done only after all air is removed from the introducer. If performed, the infusion should be done for flushing purposes only and ***NOT*** for delivering therapy or monitoring blood pressure.

CAUTIONS

⚠	Handle with care. The Impella® Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.
⚠	Patients with aortic stenosis or other abnormal aortic valve performance may be compromised by the use of the Impella® Catheter. Patients with aortic valve disease should be observed for aortic insufficiency.
⚠	Partial circulatory support with Impella® has been associated with more extensive use of rotational atherectomy. Extensive use of rotational atherectomy has been associated with a periprocedural increase in cardiac biomarkers indicative of myocardial injury. Rotational atherectomy, with or without the use of hemodynamic support, should be used in accordance with the manufacturer's instructions for use.
⚠	Physicians should exercise special care when inserting the Impella® Catheter in patients with known or suspected unrepaired abdominal aortic aneurysm or significant descending thoracic aortic aneurysm or dissection of the ascending, transverse, or descending aorta.
⚠	Use only original accessories and replacement parts supplied by Abiomed.
⚠	Do ***NOT*** use damaged or contaminated connector cables.
⚠	To prevent device failure, do ***NOT*** start the Impella® Catheter until the guidewire has been removed.
⚠	Do ***NOT*** remove the Impella® Catheter over the length of the guidewire.
⚠	When replacing the purge cassette, the replacement process must be completed within 2 minutes. The Impella® Catheter may be damaged if replacement takes longer than 2 minutes.
⚠	To prevent malfunction of the Automated Impella® Controller, avoid long-term exposure to direct sunlight and excessive heat (40°C).
⚠	To prevent overheating and improper operation, do ***NOT*** block the cooling vents of the Automated Impella® Controller while it is operating.
⚠	Do ***NOT*** kink or clamp the Impella® Catheter or the peel-away introducer.
⚠	During case start, make sure the yellow luer connection between the purge tubing and Y connector is tightened and not leaking.
⚠	The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Automated Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.
⚠	Minimize exposure of Impella® System components to sources of electromagnetic interference (EMI). Exposure to sources of EMI, such as cell phones and two-way radios, may cause operational interference. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source.

Cautions

Cautions indicate situations in which equipment may malfunction, be damaged, or cease to operate. The yellow symbol ⚠ appears before caution messages.

- Operation of Impella® System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and system components.
- Have a backup Automated Impella® Controller, purge cassette, connector cable, and Impella® Catheter available in the unlikely event of a device failure.
- Do ***NOT*** use the bed mount as a handle.
- Do ***NOT*** alter the Impella® Introducer kit in any way.
- Aspiration and saline flushing of the Impella® Introducer kit sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation.
- Indwelling introducer sheaths should be internally supported by a catheter or dilator.
- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve, resulting in blood flow through the valve.
- Never advance the guidewire or sheath when resistance is met. Determine the cause of resistance using fluoroscopy and take remedial action.
- When injecting or aspirating through the sheath, use the sideport only.

2 INDICATIONS, CONTRAINDICATIONS, AND POTENTIAL ADVERSE EVENTS

INDICATIONS (UNITED STATES) 2.1

CONTRAINDICATIONS (UNITED STATES) 2.1

POTENTIAL ADVERSE EVENTS (UNITED STATES) 2.2

INDICATIONS (UNITED STATES)

The Impella CP® Circulatory Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The Impella CP® Circulatory Support System also provides pressure measurements which are useful in determining intravascular pressure.

The Automated Impella® Controller is intended to be used by trained healthcare professionals in healthcare facilities and medical transport (ie, ambulance, helicopter, or fixed-wing aircraft) environments.

CONTRAINDICATIONS (UNITED STATES)

Patients with aortic stenosis or other abnormal aortic valve performance may be compromised by the use of the Impella® Catheter. Patients with aortic valve disease should be observed for aortic insufficiency.

- Mechanical aortic valve or heart constrictive device
- Aortic valve stenosis/calcification (graded as ≥ +2 equivalent to an orifice area of 1.5 cm^2 or less)
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as ≥ +2)
- Severe peripheral arterial obstructive disease that would preclude Impella® device placement

POTENTIAL ADVERSE EVENTS (UNITED STATES)

- Aortic insufficiency
- Aortic valve injury
- Arrhythmia
- Atrial fibrillation
- Bleeding
- Cardiogenic shock
- Cardiac tamponade
- Cerebral vascular accident (CVA) / Stroke
- Death
- Device malfunction
- Hemolysis
- Hepatic failure
- Insertion site infection
- Myocardial infarction
- Perforation
- Renal failure
- Respiratory dysfunction
- Sepsis
- Thrombocytopenia
- Thrombotic vascular (non-CNS) complication
- Transient ischemic attack (TIA)
- Vascular injury
- Ventricular fibrillation
- Ventricular tachycardia

3 THE IMPELLA® CATHETER AND AUTOMATED IMPELLA® CONTROLLER

OVERVIEW **3.1**

Reusable System Components 3.2

Single-use System Components 3.2

Impella® Set-up and Insertion Kit 3.2

System Configurations 3.3

IMPELLA® CATHETER **3.4**

AUTOMATED IMPELLA® CONTROLLER **3.6**

PURGE CASSETTE **3.7**

ACCESSORIES **3.9**

OVERVIEW

The Impella® Catheter is an intravascular microaxial blood pump that supports a patient's circulatory system. The Impella® Catheter is inserted percutaneously through the femoral artery and into the left ventricle (see Figure 3.1).

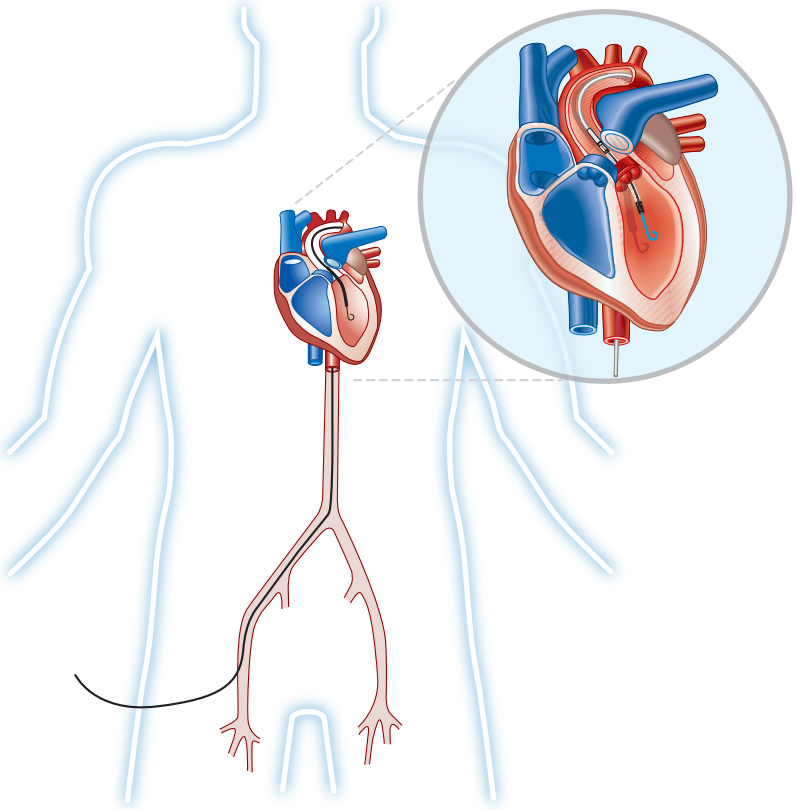

Figure 3.1 Impella® Catheter in the Heart

When properly positioned, the Impella® Catheter delivers blood from the inlet area, which sits inside the left ventricle, through the cannula, to the outlet opening in the ascending aorta. Physicians and device operators monitor the correct positioning and functioning of the Impella® Catheter on the display screen of the Automated Impella® Controller.

This section describes the components of the Impella® Catheter and the Automated Impella® Controller, as well as the accessory components.

REUSABLE SYSTEM COMPONENTS

The Impella® System consists of the following reusable components:

- Automated Impella® Controller—provides the user interface, alarm indications, and portable battery
- Automated Impella® Controller cart—for easy transport of the Automated Impella® Controller

SINGLE-USE SYSTEM COMPONENTS

The Impella® System also includes the following single-use components:

- Impella® Catheter
- Purge cassette
- Introducer kit
- 0.018 inch, 260 cm placement guidewire
- Connector cable

IMPELLA® SET-UP AND INSERTION KIT

The components of the Impella® System are packaged into a single box called the Impella® Set-up and Insertion kit. Table 3.1 describes the contents of this kit.

Table 3.1 Impella® Set-up and Insertion Kit Components

The Impella® Set-up and Insertion kit contains the following:

- Impella® Catheter
- 0.018 inch, 260 cm placement guidewire
- Connector cable
- Purge cassette
- Introducer kit
  - » 14 Fr peel-away introducer
  - » 8 Fr, 10 Fr, and 12 Fr supplemental dilators
  - » 0.035 inch stiff access guidewire

SYSTEM CONFIGURATIONS

Figure 3.2 illustrates how the Automated Impella® Controller connects to the Impella® Catheter and accessory components in the initial set-up configuration.

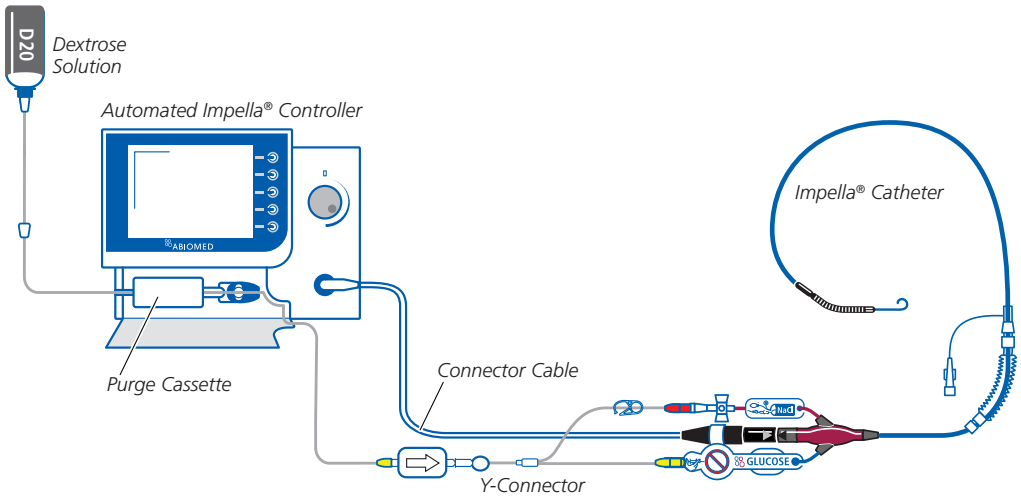

Figure 3.2 Set-up Configuration of the Automated Impella® Controller, Impella® Catheter, and Accessories

Figure 3.3 illustrates the standard configuration of the Impella® Catheter, Automated Impella® Controller, and accessory components.

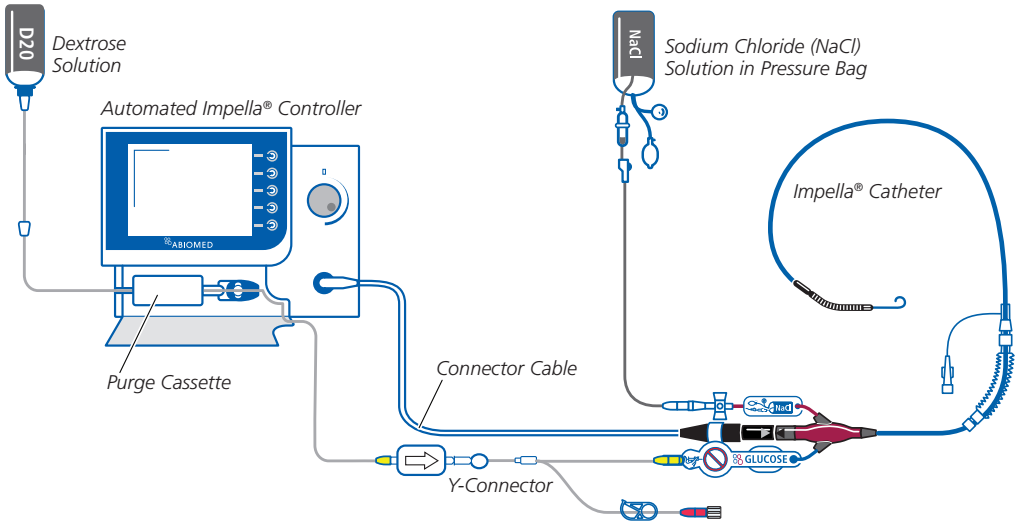

Figure 3.3 Standard Configuration of the Automated Impella® Controller, Impella® Catheter, and Accessories

IMPELLA® CATHETER

The Impella® Catheter is an intravascular microaxial blood pump that delivers a mean flow of up to 3.3 liters of blood per minute from the left ventricle into the aorta. Figure 3.4 illustrates the Impella® Catheter. Table 3.2 describes each component from the pigtail at one end to the check valve on the other end.

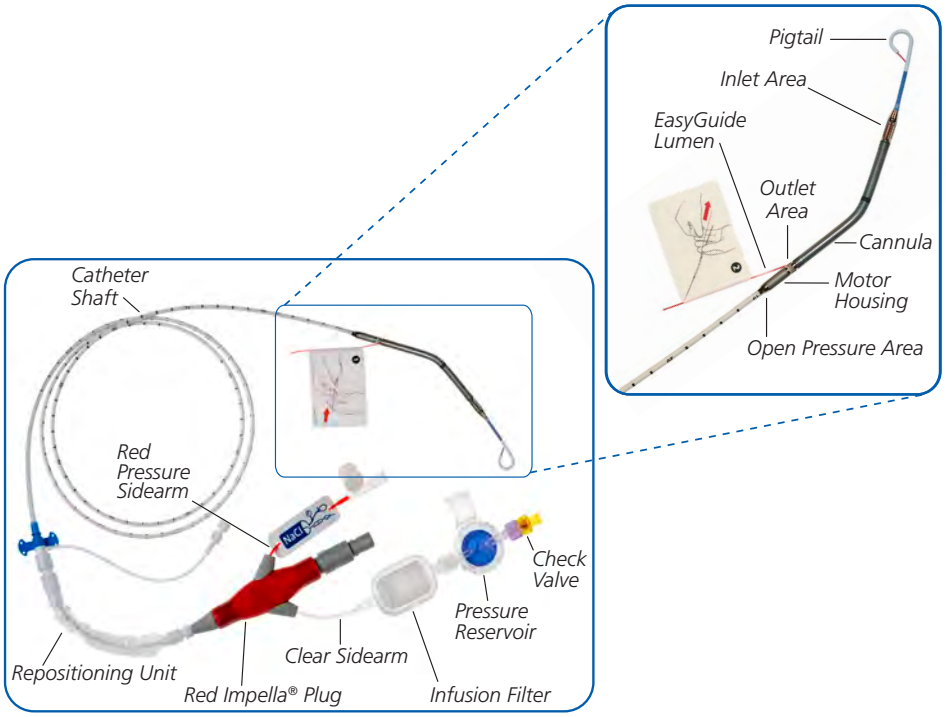

Figure 3.4 Impella® Catheter

Table 3.2 Impella® Catheter Components

Component	Description
Pigtail	The 6 Fr pigtail is attached to the cannula at the distal end of the inlet area. It assists with stabilizing the catheter in the correct position in the left ventricle.
Inlet area	The inlet area, located at the distal tip of the cannula, has four openings (windows) that allow blood to be drawn into the inlet and channeled through the cannula.
Radiopaque marker	The radiopaque marker on the catheter shaft is visible with fluoroscopy and, when properly positioned, appears at the level of the aortic valve annulus
Cannula	The 14 Fr cannula has a spiral-shaped reinforced body that is shaped in a 35-degree angle. The cannula is made of nitinol and covered in polyurethane.
Outlet area	The proximal end of the cannula is attached to the outlet area where the blood exits the cannula.
EasyGuide lumen	The red loading lumen, which runs from the tip of the pigtail through the outlet area of the cannula, facilitates loading the catheter onto the guidewire

Table 3.2 Impella® Catheter Components (continued)

Component	Description
Motor housing	The 14 Fr motor housing consists of an encapsulated motor.
Open pressure area	The open pressure area is an opening located between the motor housing and the distal end of the catheter shaft.
Catheter shaft	A 9 Fr catheter shaft is located between the motor housing and the red Impella® plug. The lumen of the catheter shaft contains a purge lumen, a pressure measurement lumen, and an electrical cable. The catheter shaft has longitudinal and transversal marks: • The longitudinal mark along the inner radius shows correct position of the 0.018 inch, 260 cm placement guidewire once backloaded on the Impella® Catheter. • The transversal marks at 1 cm intervals with numbers every 5 cm aid in proper positioning.
Repositioning unit	The repositioning unit consists of a sheath, an anticontamination sleeve with an anchoring ring, and suture pads. • The sheath (with hemostatic valve) is graduated from 9 Fr to 13 Fr. It is located on the catheter shaft and allows repositioning of the catheter. • The anchoring ring of the anticontamination sleeve secures the sheath to the catheter. • The StatLock® compatible suture pads help secure the repositioning sheath to the patient's skin.
Red Impella® plug	The red Impella® plug at the proximal end of the catheter connects the catheter to the Automated Impella® Controller through a connector cable. It contains: • A pressure transducer that translates pressure for the pressure lumen proximal to the motor • Memory that retains operating parameters in case the patient needs to be transferred to another controller • The placement signal lumen that allows for pressure and waveform displays It has two sidearms: a red pressure sidearm and a clear sidearm.
Red pressure sidearm	The red pressure sidearm is attached to a standard pressure bag and is used to prime the line of the pressure measurement system.
Clear sidearm	The clear sidearm is attached to the purge cassette tubing. It leads to the infusion filter, the pressure reservoir, and the check valve.
Infusion filter	The infusion filter prevents bacterial contamination and air from entering the purge lumen.
Pressure reservoir	The pressure reservoir includes a flexible rubber diaphragm that provides additional filling volume by means of an expansion chamber during purge solution change.
Check valve	The yellow check valve ensures that purge fluid does not flow in the reverse direction when the purge solution is exchanged.

Repositioning Sheath: Inner vs Outer Diameter

The repositioning sheath has a graduated inner diameter of 9 Fr to 13 Fr. The outer diameter is graduated from 11 Fr to 15 Fr.

AUTOMATED IMPELLA® CONTROLLER

Automated Impella® Controller Battery Power

The controller can operate on its internal lithium-ion (Li-Ion) battery for at least 60 minutes when fully charged.

The Automated Impella® Controller (see Figure 3.5) provides three vital functions to the operation of the Impella® Catheter:

- The controller provides an interface for monitoring and controlling the function of the Impella® Catheter
- The controller provides a fluid purge to the Impella® Catheter
- The controller provides backup power when the Impella® System is operated away from AC power

The controller weighs 26 lbs (11.8 kg) and can operate on its internal battery for at least 60 minutes when fully charged.

Automated Impella® Controller operation is described in detail in section 4 of this manual.

Automated Impella® Controller Power Cord

Use caution when moving equipment to prevent damaging the controller's power cord.

Figure 3.5 Automated Impella® Controller – Front View

PURGE CASSETTE

Do not use saline in the purge system.

The purge cassette delivers rinsing fluid to the Impella® Catheter. The purge fluid (typically 20% dextrose solution) flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor. When the purge cassette is properly installed in the Automated Impella® Controller, the Abiomed logo is upright and facing you. Figure 3.6 illustrates the purge cassette and related components. Table 3.3 describes each component.

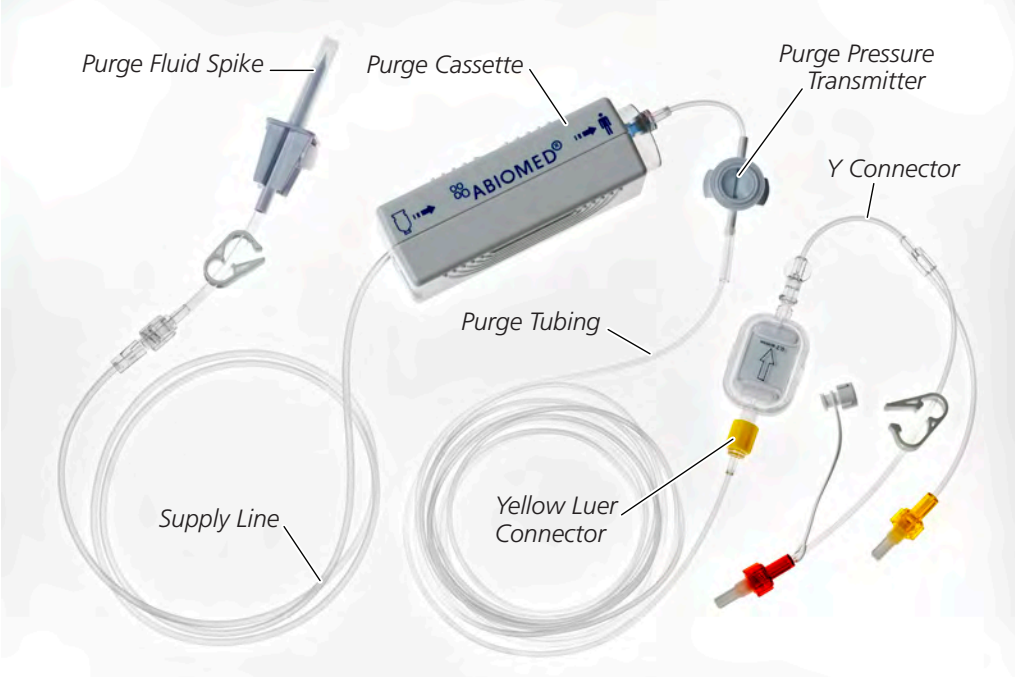

Figure 3.6 Purge Cassette

Y Connector for Set-up Configuration

The Y connector attached to the purge tubing is used for the initial set-up configuration of the Impella® System. Switch to the standard configuration as soon as practical..

Table 3.3 Purge Cassette Components

Component	Description
Purge fluid spike	One end spikes the purge fluid bag and the other end connects the bag to the purge cassette supply line
Supply line	Carries fluid from the purge fluid bag to the purge cassette
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor
Purge pressure transmitter	Transmits pressure to the controller based on the purge pressure in the purge tubing; a sensor in the controller measures the pressure so that it can be displayed on the screen and used by the purge pressure algorithm to maintain the purge pressure
Purge tubing	Carries purge fluid from the purge cassette to the Impella® Catheter
Yellow luer connector	Connects the purge tubing to the Y connector at case start and to the check valve (yellow luer lock) on the Impella® Catheter during system change
Y connector	Adapter that connects the purge tubing to the sidearms of the Impella® Catheter during case start. The Y connector consist of: • Yellow luer that connects to the clear sidearm • Red luer that connects to the red sidearm • Cap for the red luer when it is disconnected from the sidearm for transfer to the standard configuration • Clamp for the purge tubing leading to the red sidearm • Rectangular antibacterial air filter

ACCESSORIES

Table 3.4 illustrates and describes the accessories used with the Impella® Catheter and Automated Impella® Controller.

Table 3.4 Impella® Catheter and Automated Impella® Controller Accessories

Component	Description
	The white connector cable connects the Impella® Catheter to the Automated Impella® Controller. Clips on the cable are used to secure the purge tubing to the cable. • The socket at the black end of the cable connects to the Impella® Catheter plug. • The white plug at the opposite end of the cable is inserted into the blue catheter plug on the front of the Automated Impella® Controller.
Figure 3.7 White Connector Cable	
	The introducer kit is used to gain arterial access for the Impella® Catheter. It contains: • 14 Fr peel-away introducer—with hemostatic valve for tight fit around components and single-step "break-away" configuration • 8 Fr, 10 Fr, and 12 Fr dilators—easy to insert and remove with soft design for atraumatic approach into femoral artery • 0.035 inch stiff access guidewire
Figure 3.8 Introducer Kit	
	The 0.018 inch, 260 cm placement guidewire is used for the placement of the catheter. The guidewire has a radiopaque, shapable tip.
Figure 3.9 0.018 inch, 260 cm Placement Guidewire	

Guidewire Use

It is important to use only the guidewire supplied with the system.

Component	Description
	Hospital Provided: Dextrose solution (typically 20% dextrose in water with 50 IU/mL of heparin) is used as the purge fluid through the Impella® Catheter.

Figure 3.10 Dextrose Solution

The Automated Impella® Controller cart holds the Automated Impella® Controller. The cart has wheels for easy transport of the controller and a storage basket. (For more information, including assembly instructions, refer to the Automated Impella® Controller cart instructions for use.)

Figure 3.11 Automated Impella® Controller Cart

4 USING THE AUTOMATED IMPELLA® CONTROLLER

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AUTOMATED IMPELLA® CONTROLLER FEATURES **4.2**

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PLACEMENT SCREEN **4.9**

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INFUSION HISTORY SCREEN **4.11**

MOBILE OPERATION **4.12**

OVERVIEW

The Automated Impella® Controller is the primary user control interface for the Impella® Catheter. It controls the Impella® Catheter performance, monitors the catheter for alarms, and provides real-time catheter position information regarding the location of the catheter across the aortic valve. The controller can be powered by AC power or can operate on internal battery power for at least 60 minutes when fully charged.

This section of the manual discusses Automated Impella® Controller features and displays.

AUTOMATED IMPELLA® CONTROLLER FEATURES

IMPORTANT NOTE: The underside of the Automated Impella® Controller has a battery switch to turn on the batteries. This switch is turned off for shipping purposes. Before operating the Automated Impella® Controller for the first time, make sure you turn this switch on. If the battery switch is not turned on, the Automated Impella® Controller will not be able to operate on battery power.

Figure 4.1 illustrates the features on the front of the Automated Impella® Controller. These features are described in Table 4.1.

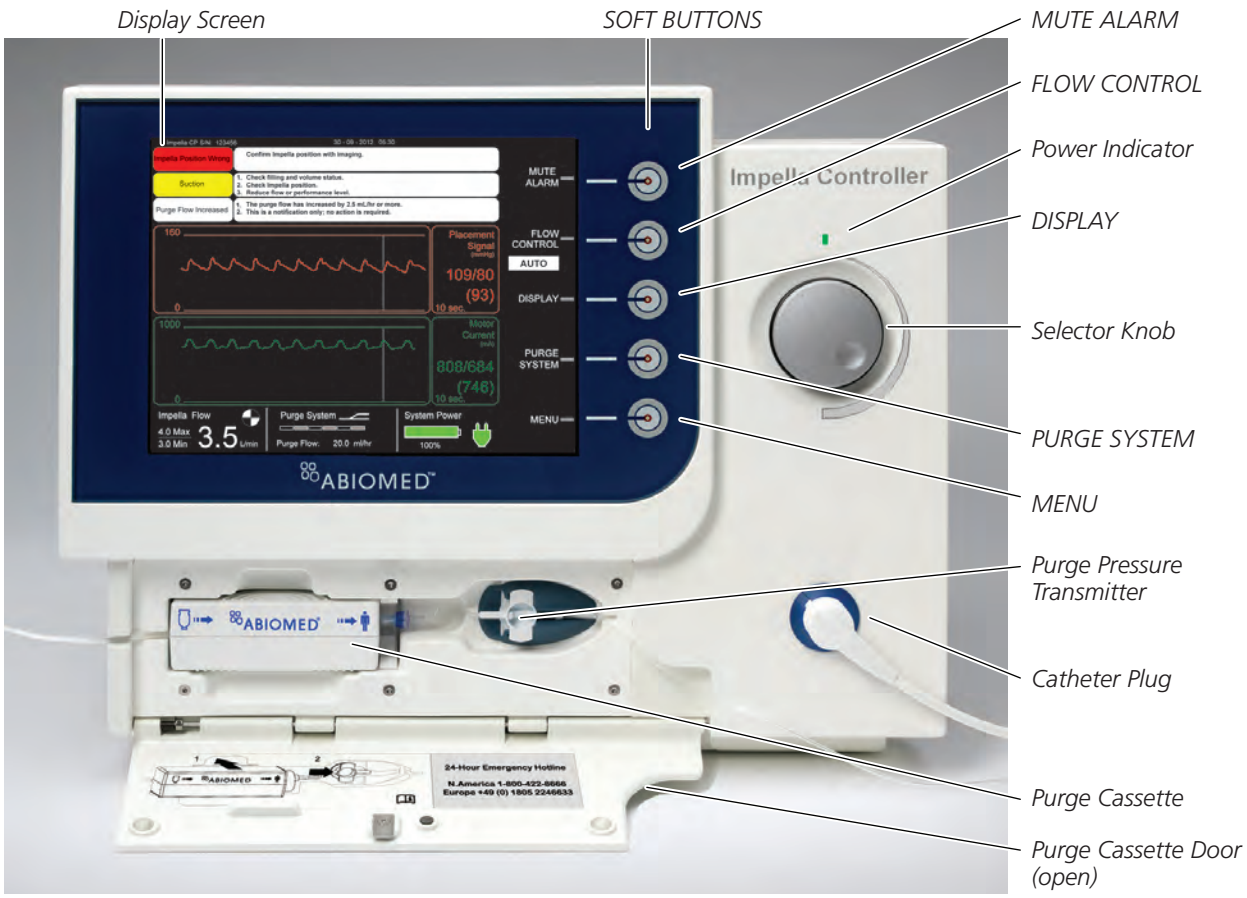

Figure 4.1 Automated Impella® Controller Features – Front View

Table 4.1 Automated Impella® Controller Front View Features

Feature	Description
Display screen	Displays user information, including the labels for the soft buttons. (Display screen elements described in detail later in this section.)
Soft buttons	Display, open, and close menus. The function for each soft button is defined by labels adjacent to the button on the display screen; function changes depending on the screen. (Soft button functions are described in Table 4.3.) When the Impella® Catheter is running, the default soft button labels are as follows: • **MUTE ALARM** • **FLOW CONTROL** • **DISPLAY** • **PURGE SYSTEM** • **MENU**
Power indicator	LED light above the selector knob; indicates the power status of the Automated Impella® Controller. • Green light—controller is on and plugged into AC power or running on battery power • Amber light—controller is off but plugged into AC power • No light—controller is off and not plugged into AC power
Selector knob	Rotating push button; turn clockwise and counterclockwise to navigate through menu items; push to make a selection.
Purge pressure transmitter	A flexible diaphragm on the purge cassette tubing used to monitor purge pressure and regulate purge flow.
Catheter plug	Connection point on the controller for the connector cable that connects to the Impella® Catheter.
Purge cassette	Contains the components for delivering the purge fluid; maintains the pressure barrier between the blood and the motor to prevent blood from entering the motor. (The purge cassette and its components are described in section 3 of this manual.)
Purge cassette door	Spring-loaded door that opens to provide access to the purge cassette.

Display Options

If equipped with a VGA connector, the controller can be connected to a monitor to display information on another screen as described under "Slave Monitor Connection" in section 8 of this manual.

Selector Knob Function

***Rotate** the selector knob on the controller to navigate through menu items.*
***Push** the selector knob to confirm your selection.*

Figure 4.2 illustrates the features on the left and right sides of the Automated Impella® Controller. These features are described in Table 4.2.

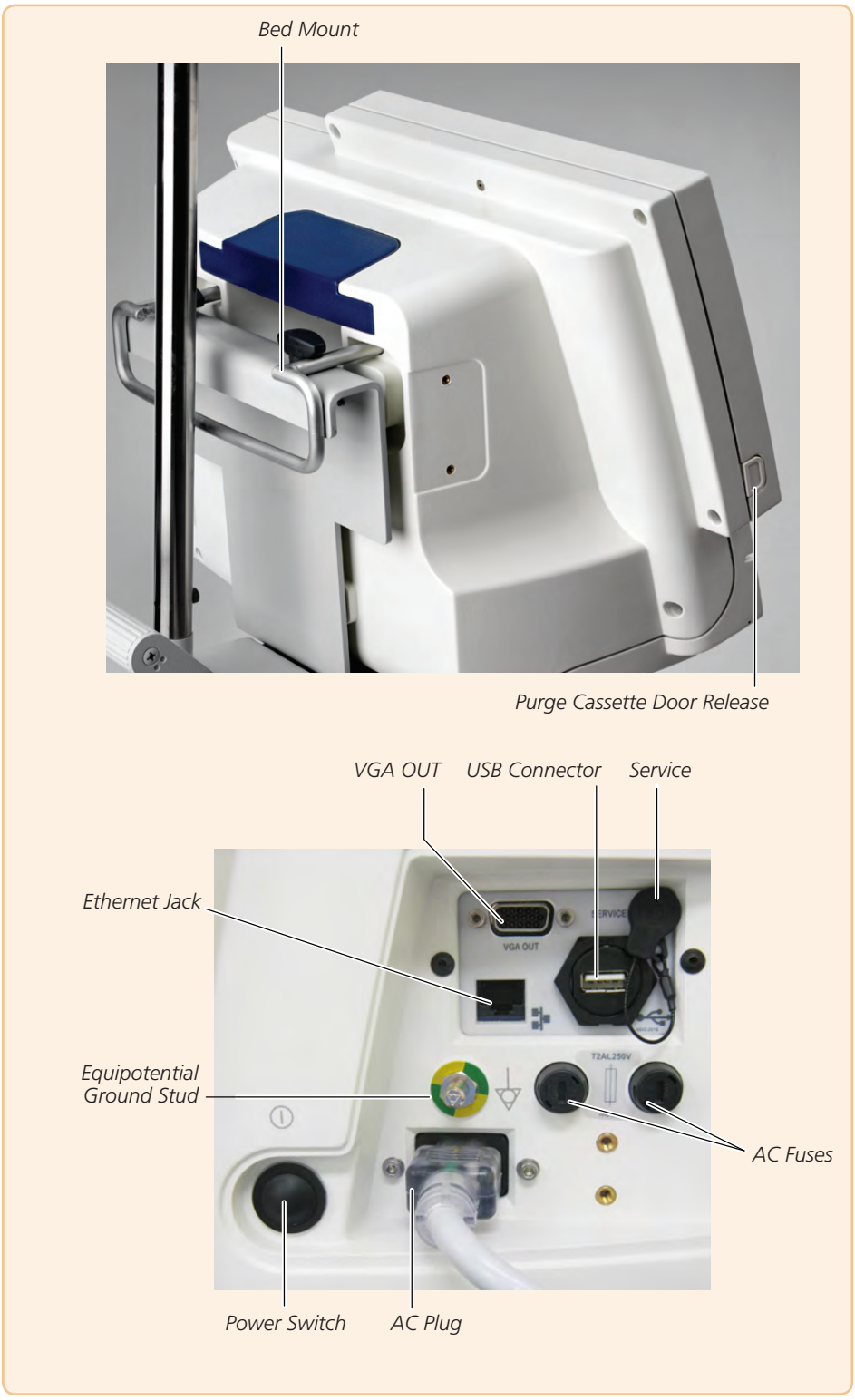

Figure 4.2 Automated Impella® Controller Features – Side Views

Table 4.2 Automated Impella® Controller Side View Features

Feature	Description
Bed mount	Metal bracket on the back of the controller; attaches controller to the cart or bed
Purge cassette door release	Button located on the left side of the controller; press to open the purge cassette door
VGA OUT	Connection for connecting the controller to another monitor to slave the display
USB connector	Interface for data transfer by Abiomed maintenance or service personnel
Service	Connection used by Abiomed maintenance or service personnel
AC fuses	Electrical safety device in the event of current overload
AC plug	Connection point on the controller for the AC power cord
Power switch	Button that turns the controller on or off • ON: Press and hold the power switch for 3 seconds • OFF: (1) Disconnect the Impella® Catheter from the Automated Impella® Controller (2) Press and hold the power switch for 3 seconds (3) A pop-up confirmation box will appear (4) Press **OK** using the selector knob to confirm that the controller should be turned off NOTE: Holding down the power switch for longer than 30 seconds during operation will cause the controller to initiate an emergency shutdown
Equipotential ground stud	Used to ground the Automated Impella® Controller according to hospital procedures
Ethernet jack	Connection for downloading data

HOME SCREEN

The home screen displays operating parameters and information for the entire Impella® System. Figure 4.3 illustrates the home screen. Each element of the display is described in Table 4.3.

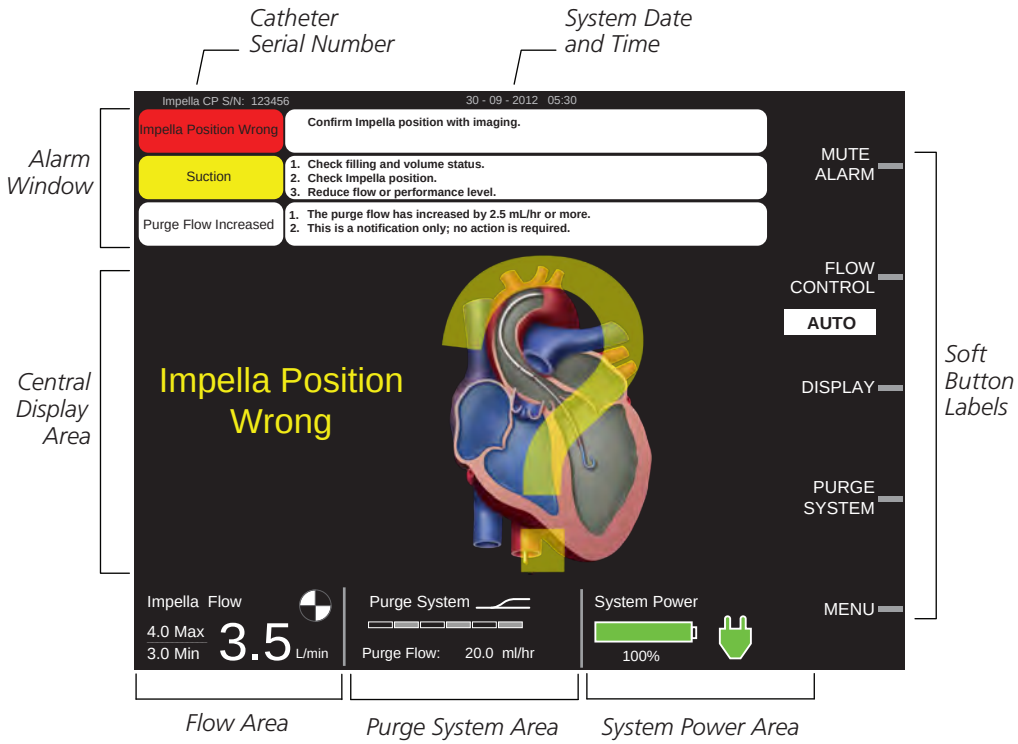

Figure 4.3 Home Screen

Table 4.3 Automated Impella® Controller Display Elements

Display Element	Description
Alarm window	The alarm window displays up to 3 alarms simultaneously, in order of priority from top to bottom. For each alarm, the alarm window displays: • Alarm header – displayed in the left column; window is color-coded red for critical alarms, yellow for serious alarms, white for advisory notifications, gray for resolved alarms • Detailed text – up to 3 lines of instructions for resolving the alarm condition are displayed in the right column of the alarm window next to the alarm header and subhead information (See section 7 of this manual for further discussion of alarms.)
Catheter serial number	Displayed in the upper left of the display screen if a catheter is connected to the controller.
System date and time	The current date (DD-MM-YYYY) and time (24-hour format; HH:MM) are displayed in the upper center of the screen display. (In this example it is September 30, 2012 at 5:30am.)

Table 4.3 Automated Impella® Controller Display Elements (continued)

Display Element	Description
Mute alarm indicator	Displayed in place of the words "MUTE ALARM" when an alarm is silenced. (See section 7 of this manual for more information about the mute alarm function; Figure 7.1 illustrates the mute alarm indicator.) • Yellow bell with red X displayed when an alarm is muted • Not displayed when an alarm is active (but not muted) or when there are no active alarms
Soft button labels	The soft buttons on the Automated Impella® Controller have corresponding labels adjacent to them on the display screen. These labels change depending on the type of screen displayed. (Refer to Appendix C in this manual for more details about the menu structure.) **MUTE ALARM** • Mutes (silences) active alarms **FLOW CONTROL** (or **NEXT**) • **FLOW CONTROL** – Allows you to control the flow of the Impella® Catheter • **NEXT** – Advances to the next screen **DISPLAY** (or **BACK**) • **DISPLAY** – Brings up the Display menu for viewing waveforms and navigating to other screen displays • **BACK** – Returns to the previous screen **PURGE SYSTEM** (or **EXIT**) • **PURGE SYSTEM** – Brings up the Purge System menu for changing the purge fluid, purge cassette, or purge system; de-airing the purge system; or transferring to the standard configuration • **EXIT** – Exits the current procedure **MENU** • **MENU** – Brings up a menu of options related to controller settings, alarm history, and starting a case
System power area	System power information is displayed to the right of the purge system information on the bottom of the display screen. Battery status – Bar within battery symbol indicates the overall remaining capacity of the batteries • Full green bar for fully charged battery • Partial green bar for battery that is at least 50% charged • Partial yellow bar for battery that is between 16% and 50% charged • Partial red bar for battery that is less than or equal to 15% charged • Moving gray bar for battery that is in charging mode • Percentage of battery power remaining displayed below the battery icon AC plug indicator • Green plug indicates that the controller is running on AC power • Gray plug with a red X indicates no AC power detected and the controller is running on battery power

Purge System Stabilization

The purge system must stabilize after case start, a purge procedure, or resolution of a purge alarm. During this time, it may take up to 3 minutes for purge system information to display on the screen.

Table 4.3 Automated Impella® Controller Display Elements (continued)

Display Element	Description
Purge system area	Information about the purge system is displayed to the right of the flow area at the bottom of the display screen. Purge system marquee—scrolls from left to right when purge system is operating • Slow scrolling represents normal purge flow rate • Fast scrolling represents bolus flow rate and priming flow rate Y connector icon • Appears above the purge system marquee when the Impella® System is configured using the Y connector in the set-up configuration Purge flow • Current purge flow displayed in mL/hr below the purge system marquee if the purge flow is known • Not displayed when the purge system is stabilizing, when there is no purge cassette, or when the procedure has not yet started
Flow area	Information about Impella® Catheter flow is displayed in the lower left corner of the display screen. Max/Min • Max/Min displays the range for the flow rate Current flow rate • Mean catheter flow displayed in liters per minute (L/min)—the numbers appear in *white* if the catheter position is correct; *yellow* if the catheter position is incorrect or unknown • If the system is unable to calculate flow, a yellow triangular caution icon is displayed with the message "Flow Calculation Disabled" Catheter operation icon • The circular catheter operation icon rotates when the Impella® Catheter is running
Central display area	On the home screen, the central display area displays a heart pictogram and Impella® Catheter position indicator message. Heart pictogram appears in the center of the home screen display. • Provides a visual representation of the current Impella® Catheter position • Overlaid with a translucent yellow "?" when the controller cannot determine catheter position, position is wrong, and placement monitoring is suspended or disabled Impella® Catheter position indicator message displayed to the left of the heart icon. • Displays "Impella Position OK" in green when catheter position is correct • Displays "Impella Position Unknown" in yellow when catheter position is unknown • Displays "Impella Position in Ventricle" in yellow when catheter is in the ventricle • Displays "Impella Position Wrong" in yellow when catheter position is incorrect • Displays "Placement Monitoring Suspended" in yellow when there is a fault in the sensor • Displays "Placement Monitoring Disabled" in yellow when you turn off placement monitoring through the menu

PLACEMENT SCREEN

The placement screen (see Figure 4.4) displays real-time operating data for the system. The screen displays the placement signal and motor current waveforms as well as the maximum/minimum and average values for each waveform in the central display area of the screen.

Use the **DISPLAY** soft button to navigate to the placement screen.

Figure 4.4 Placement Screen

Figure 4.4 shows two time-based waveform signals from different sources.

- Placement signal waveform
- Motor current waveform

PLACEMENT SIGNAL WAVEFORM

The placement signal waveform displays a pressure measurement that is useful for determining the location of the open pressure area of the catheter with respect to the aortic valve. The placement signal is used to verify whether the Impella® Catheter is in the aorta or in the ventricle by evaluating the current pressure waveform as an aortic or ventricular waveform. The scale for the placement signal waveform is displayed to the left of the waveform. The default scaling is 0–160 mmHg. It can be adjusted in 20 mmHg increments, with a minimum upper limit of 100 mmHg and a maximum upper limit of 240 mmHg for the Impella® Catheter.

To the right of the waveform is a display that labels the waveform, provides the units of measurement, and shows the maximum and minimum values and the average value from the samples received. At the bottom of that window is the time scale, which you can set by pressing the **DISPLAY** soft button.

Retrograde Flow

A setting of P-0 will result in retrograde flow when the Impella® Catheter is placed across the aortic valve. Retrograde flow may also occur at P-1.

MOTOR CURRENT WAVEFORM

Motor current is a measure of the energy intake of the Impella® Catheter motor. The energy intake varies with motor speed and the pressure difference between the inlet and outlet areas of the cannula. Motor current (see Figure 4.4) provides information about the catheter position relative to the aortic valve. When the Impella® Catheter is positioned correctly, with the inlet area in the ventricle and the outlet area in the aorta, the motor current is pulsatile because the pressure difference between the inlet and outlet areas changes with the cardiac cycle. When the inlet and outlet areas are on the same side of the aortic valve, the motor current will be dampened or flat because there is little or no pressure difference between the inlet and outlet areas.

The scale for the motor current waveform is displayed to the left of the waveform. The default scaling is 0–1000 mA. It is adjustable in 100 mA increments for the Impella® Catheter, with a minimum difference between upper and lower limits of 200 mA and a maximum difference of 1000 mA.

To the right of the waveform is a display that labels the waveform, provides the units of measurement, and shows the maximum and minimum values and the average value from the samples received. You can set the time scale at the bottom of that window by pressing the **DISPLAY** soft button.

PURGE SCREEN

The purge screen (see Figure 4.5) displays purge system data. In the central display area of the screen, the purge flow rate and purge pressure are plotted as a function of time. To the right of the plots, the current purge flow rate and purge pressure are displayed.

Use the **DISPLAY** soft button to navigate to the purge screen.

Figure 4.5 Purge Screen

PURGE FLOW

The purge flow rate delivered by the purge cassette is displayed in mL/hr. The standard scale for the purge flow (0–30 mL/hr) is displayed to the left of the purge flow plot. The maximum value on this scale can be adjusted from 20 mL/hr to 200 mL/hr in increments of 10 mL/hr.

To the right of the plot is a display that labels the plot and shows the most recent value update. You can set the time scale at the bottom of the window by pressing the **DISPLAY** soft button.

An advisory alarm will be displayed in the alarm window when the purge flow rate increases or decreases by 2.5 mL/h. The message is intended to aid patient management by alerting the clinician to changes in the rates of dextrose and heparin infusion through the purge fluid. The alarm clears when you press the **MUTE ALARM** button.

PURGE PRESSURE

The Automated Impella® Controller regulates purge pressure, the pressure of the purge fluid delivered through the catheter to the motor. The purge pressure generated by the purge cassette is displayed in mmHg. The standard scale for the purge pressure (0–1500 mmHg) is displayed to the left of the purge pressure plot. The maximum value on this scale can be adjusted from 100 mmHg to 2000 mmHg in increments of 100 mmHg. An alarm appears if purge pressure falls below 300 mmHg or exceeds 1100 mmHg.

To the right of the plot is a display that labels the plot and shows the most recent value update. You can set the time scale at the bottom of the window by pressing the **DISPLAY** soft button.

Purge Flow

In the initial set-up configuration of the Impella® System, purge flow is regulated to keep the purge pressure at 600 mmHg, although it may not reach 600 mmHg in low resistance catheters in this configuration.

In the standard configuration, purge flow can range from 2 to 30 mL/hr and purge pressure can range from 300 to 1100 mmHg.

Purge Pressure Depends on System Configuration

When in the initial set-up configuration, the purge pressure is set to 600 mmHg with flows between 2 and 30 mL/hr. After switching to the standard configuration, the purge pressure is set to an ideal pressure between 300 and 1100 mmHg and flows between 2 and 30 mL/hr.

INFUSION HISTORY SCREEN

The infusion history screen displays the infusion volume as well as the amount of heparin and dextrose infused each hour. The current time period is displayed at the top of the list.

Use the **DISPLAY** soft button to navigate to the infusion history screen.

Figure 4.6 shows a sample infusion history screen.

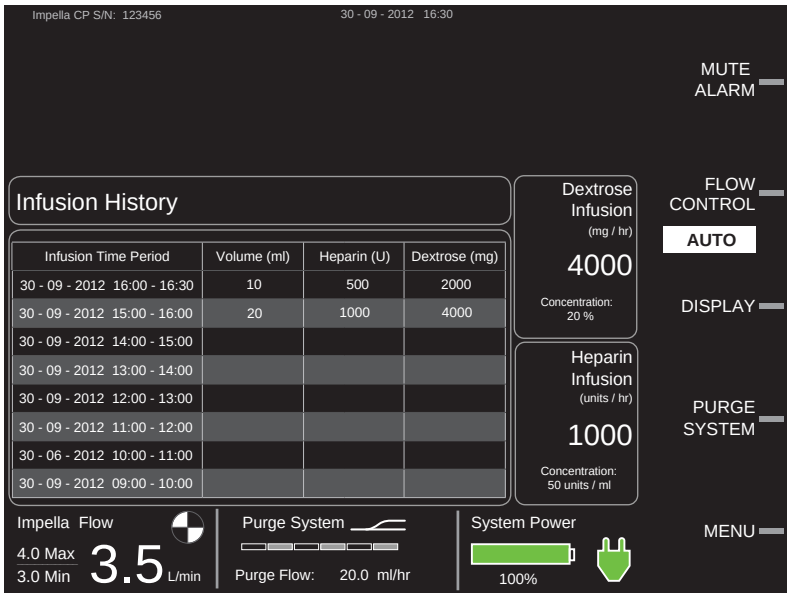
Impella CP S/N: 123456
30 - 09 - 2012 16:30
MUTE ALARM
Infusion History
Infusion Time Period | Volume (ml) | Heparin (U) | Dextrose (mg)
30 - 09 - 2012 16:00 - 16:30 | 10 | 500 | 2000
30 - 09 - 2012 15:00 - 16:00 | 20 | 1000 | 4000
30 - 09 - 2012 14:00 - 15:00
30 - 09 - 2012 13:00 - 14:00
30 - 09 - 2012 12:00 - 13:00
30 - 09 - 2012 11:00 - 12:00
30 - 06 - 2012 10:00 - 11:00
30 - 09 - 2012 09:00 - 10:00
Dextrose Infusion
(mg / hr)
4000
Concentration: 20 %
Heparin Infusion
(units / hr)
1000
Concentration: 50 units / ml
FLOW CONTROL
AUTO
DISPLAY
PURGE SYSTEM
MENU
Impella Flow
4.0 Max
3.0 Min
3.5 L/min
Purge System
Purge Flow: 20.0 ml/hr
System Power
100%

Figure 4.6 Infusion History Screen

MOBILE OPERATION

The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Automated Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.

The Automated Impella® Controller can be operated on internal battery power when it is not connected to AC power.

1. Disconnect the Automated Impella® Controller from AC power.
2. The Automated Impella® Controller beeps once every 5 minutes to alert you that it is running on battery power and a white advisory notification appears in the alarms area on the screen. The AC power icon turns gray with an X through it.
3. When the Automated Impella® Controller is connected back to AC power, the white advisory notification turns gray and the AC power icon turns green.

5 USING THE AUTOMATED IMPELLA® CONTROLLER WITH THE IMPELLA® CATHETER

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PRE-SUPPORT EVALUATION

Before initiating the procedure, evaluate the patient for factors that may prevent successful placement of the Impella® Catheter. Use imaging technology to examine the patient's vasculature and femoral access site. An echo assessment of the left ventricle is also recommended to rule out left ventricular thrombus, mechanical aortic valves, or severe aortic insufficiency.

Table 5.1 Evaluation Prior to Inserting the Impella® Catheter

Technology	Observations
• Standard traditional angiography • Magnetic resonance angiography (MRA) • Coronary computed tomography angiography (CTA) • Ultrasound • Echocardiography	• LV thrombus • Mechanical aortic valve • Aortic valve stenosis / calcification • Moderate to severe aortic insufficiency • Tortuous iliac artery • Multiple access (scar tissue) • Severe peripheral arterial obstructive disease • Obesity

ALTERNATIVE SHEATHS AND SURGICAL TECHNIQUES

If the patient has a tortuous iliac artery, an alternative 30 cm sheath can be used for insertion of the Impella® Catheter. The Impella® Catheter can also be inserted surgically. A surgical technique is described in Appendix D.

STARTUP

	Do ***NOT*** use an Impella® System if any part of the system is damaged.
	The sterile components of the Impella® System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.
	Do ***NOT*** resterilize or reuse the Impella® Catheter. It is a disposable device and is intended for single use only.
	To prevent malfunction of the Automated Impella® Controller, avoid long-term exposure to direct sunlight and excessive heat (40°C).
	To prevent overheating and improper operation, do ***NOT*** block the cooling vents of the Automated Impella® Controller while it is operating.
	The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Automated Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.
	Have a backup Automated Impella® Controller, purge cassette, connector cable, and Impella® Catheter available in the unlikely event of a device failure.

SUPPLIES NEEDED

- Automated Impella® Controller
- Impella® Catheter Set-up and Insertion kit
- Diagnostic catheter (AL1 or MP without side holes or pigtail with or without side holes)
- 5–8 Fr introducer
- Standard 0.035" x175 cm J-tip guidewire
- Standard IV infusion set
- Normal saline flush solution with pressure bag
- 500 cc bag of dextrose solution for purge solution (20% recommended; 5% to 40% acceptable) with 50 IU heparin/mL

TURNING ON THE AUTOMATED IMPELLA® CONTROLLER

To turn the controller on:

1. Press and hold the power switch on the right side of the Automated Impella® Controller for 3 seconds (see Figure 5.1).

Figure 5.1 Automated Impella® Controller Power Switch

The Automated Impella® Controller automatically performs a system test when turned on.

A display bar shows the progress of the system test. If the system test passes, the system displays the startup screen (see Figure 5.2).

If the system test fails, the controller displays a system self check failure message:

SYSTEM SELF CHECK FAILED.
CHANGE CONSOLE IMMEDIATELY.

The controller displays the reason for the system test failure at the bottom of the screen.

Battery Switch

Before operating the Automated Impella® Controller for the first time, turn on the switch on the underside of the controller to turn on the batteries.

THE STARTUP SCREEN

Check Date and Time

The current date and time appear at the top of the startup screen. Confirm that these are correct. For more information, refer to Appendix C.

The startup screen (see Figure 5.2) appears when you successfully turn on the Automated Impella® Controller.

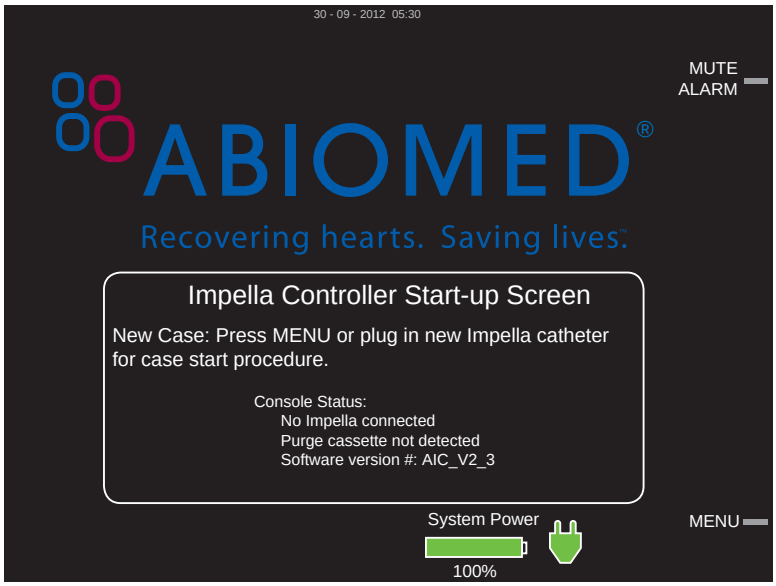


Figure 5.2 Automated Impella® Controller Startup Screen

The startup screen displays:

- The current status of the Impella® Catheter (currently not connected to the Automated Impella® Controller in Figure 5.2).
- The current status of the purge cassette (no purge cassette detected in Figure 5.2).
- The current version of the software that the Automated Impella® Controller is running.

The startup screen also displays system power information along the bottom of the screen and two active soft buttons—**MUTE ALARM** and **MENU**—along the right side of the screen.

CASE START

Fluoroscopy is required to guide placement of the Impella® Catheter. The small placement guidewire must be reliably observed at all times.

The sterile components of the Impella® System can be used only if the sterilization indicators show that the contents have been sterilized, the packaging is not damaged, and the expiration date has not elapsed.

Avoid manual compression of the inlet and outlet areas of the cannula assembly.

Do ***NOT*** remove the Impella® Catheter over the length of the guidewire.

Handle with care. The Impella® Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.

During case start, make sure the yellow luer connection between the purge tubing and Y connector is tightened and not leaking.

Do ***NOT*** kink or clamp the Impella® Catheter or the peel-away introducer.

Sensitive Medical Device

The Impella® Catheter is a sensitive medical device with extremely fine tolerances. In particular, the inlet and outlet areas of the catheter assembly may be damaged if subjected to strong external forces.

CASE START

1. Press the **MENU** soft button from the startup screen. "Case Start" is the default selection on the pop-up menu that appears on the screen.
2. Press the selector knob to select "Case Start." The controller displays the screen shown in Figure 5.3.

Two Ways to Start the Setup Procedure

*You can start the setup procedure from the **MENU** on the startup screen (as described on this page) or when a new Impella® Catheter is plugged into the controller.*

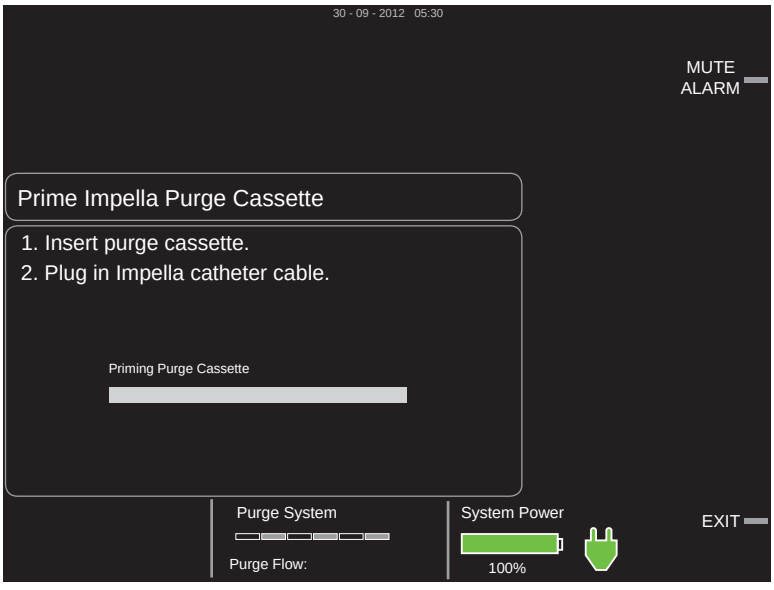


Figure 5.3 Initial Case Start Screen

INSERT PURGE CASSETTE

Shaded Steps

All shaded steps require sterile technique.

Purge Solution Bottles

If the purge solution is supplied in bottles, open the vent on the purge fluid spike and follow the same procedure as if supplied in bags.

Connect Purge Pressure Transmitter Within 10 Seconds

An alarm will appear if the purge pressure transmitter is not snapped into place within 10 seconds of inserting the purge cassette.

Close Purge Cassette Door

Once the purge cassette is installed, be sure to close the purge cassette door to prevent the purge cassette from being dislodged accidentally.

1. Open the purge cassette package.
2. Secure the red and yellow luers to the sterile field.
3. Pass the purge cassette and spike off the sterile field.
4. Spike the fluid bag/bottle.
5. Open the purge cassette door by pressing the release on the left side of the controller. Insert the purge cassette into the Automated Impella® Controller (as shown in Figure 5.4 and described in the steps that follow).

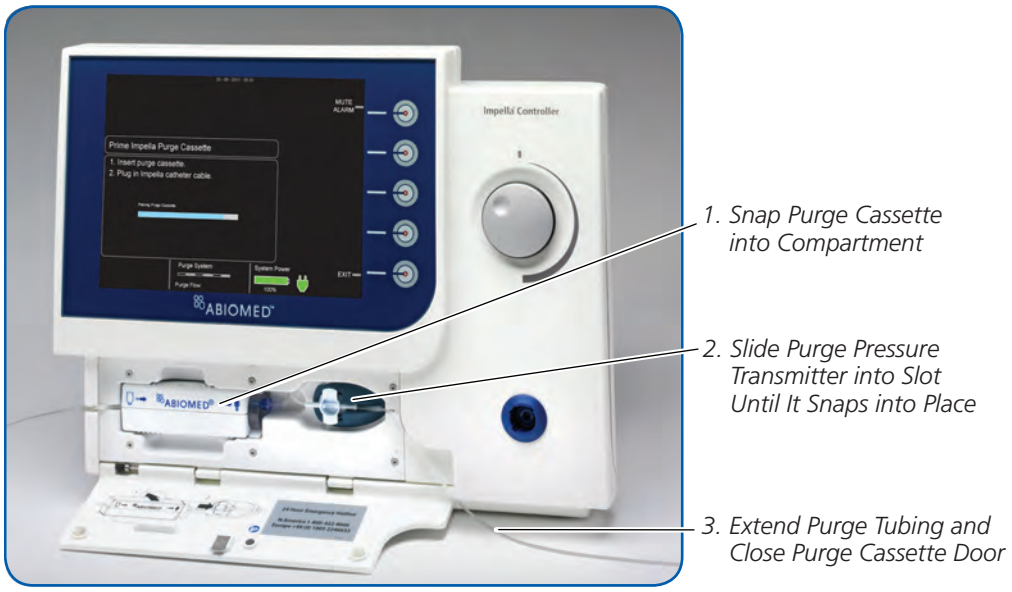

1. Snap Purge Cassette into Compartment
2. Slide Purge Pressure Transmitter into Slot Until It Snaps into Place
3. Extend Purge Tubing and Close Purge Cassette Door

Figure 5.4 Inserting Purge Cassette into Automated Impella® Controller

6. Insert the purge cassette into the compartment on the front of the controller. Follow the diagram on the inside of the purge cassette door for proper placement.
7. Slide the purge pressure transmitter into the slot to the right of the purge cassette until it snaps into place. The controller will automatically begin priming the purge cassette.
8. Extend the purge tubing and close the purge cassette door. There is sufficient room around the edges of the purge cassette door so that it will not pinch the purge tubing as it exits.
9. The controller automatically begins priming the purge cassette after it is inserted. The progress bar shown in Figure 5.3 marks the progress of the purge cassette priming.

CONNECT THE IMPELLA® CATHETER

1. Remove the Impella® Catheter from its package using sterile technique and inspect the catheter, including its connector, for damage.
2. Remove the white connector cable from its package using sterile technique.
3. Inspect the cable for damage, including damage to the connector pins at the controller end.
4. Secure the black end of the cable to the sterile field.
5. Insert the catheter plug into the connector cable socket (black end). The tab and the slot must be aligned during connection (see Figure 5.5).

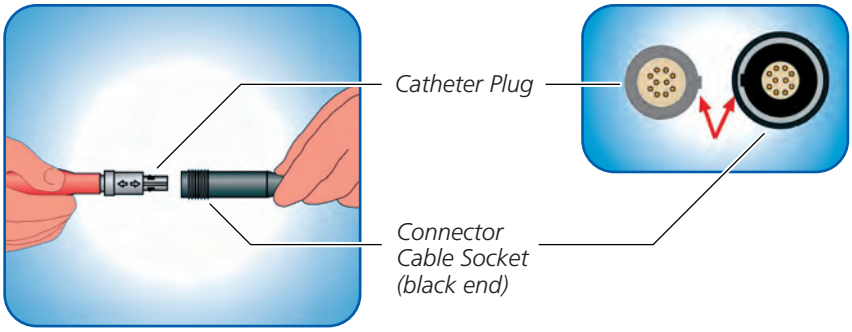


Figure 5.5 Inserting the Catheter Plug into the Connector Cable

6. Pull back on the connection to make sure that the plug has snapped into place.
7. Snap the plastic clip (located on the pressure reservoir of the clear sidearm) to the connector cable as shown in Figure 5.6.

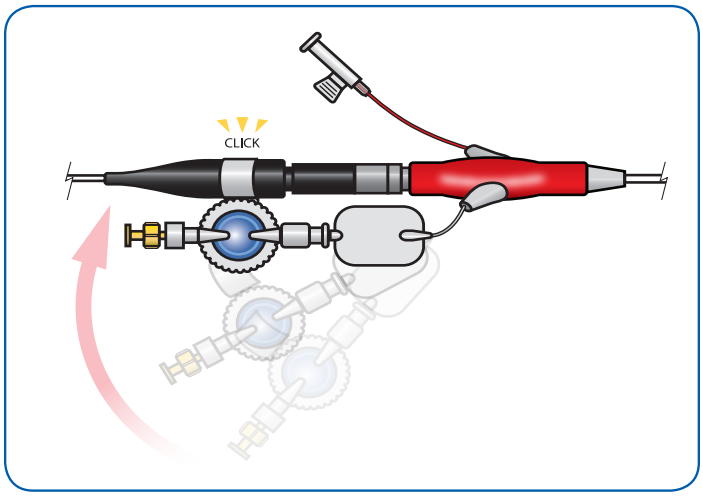


Figure 5.6 Snapping Plastic Clip to Connector Cable

8. Pass the sterile connector cable from the Impella® Catheter off the sterile field.

Important Step

Snapping the plastic clip on the pressure reservoir to the connector cable is important to prevent the tube from kinking.

9. Line up the notch on the connector cable with the notch in the blue catheter plug on the front of the Automated Impella® Controller and plug the cable into the controller.

10. Once the purge cassette is primed and the controller detects that the connector cable is plugged in, it prompts you to connect the luer(s) to the Impella® Catheter. (See Figure 5.7)

Error Screens

If you miss a step in the process of setting up the Impella® Catheter, or if you exceed the amount of time allowed to complete a step, the Automated Impella® Controller will display an error screen with instructions for continuing the setup process.

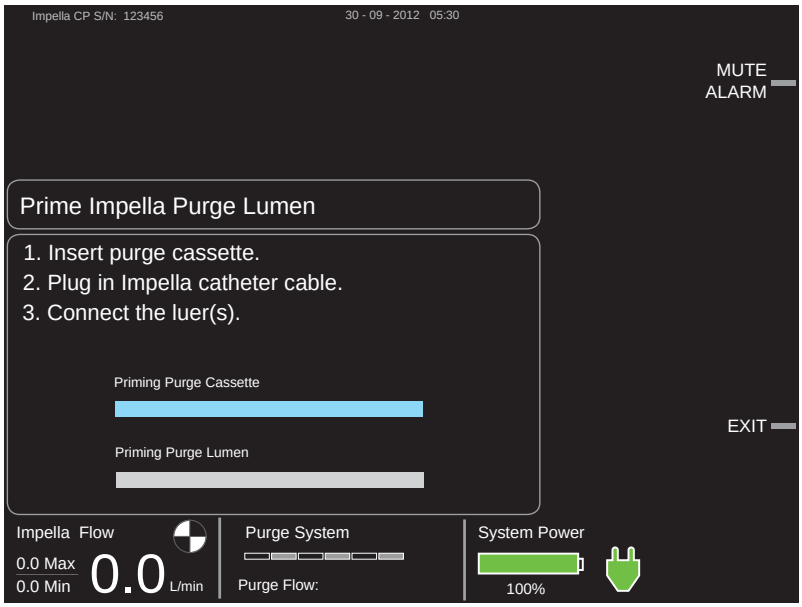


Figure 5.7 Priming the Impella Purge Lumen

11. Connect and tighten the luer(s) on the purge tubing to the Impella® Catheter sidearms as shown in Figure 5.8

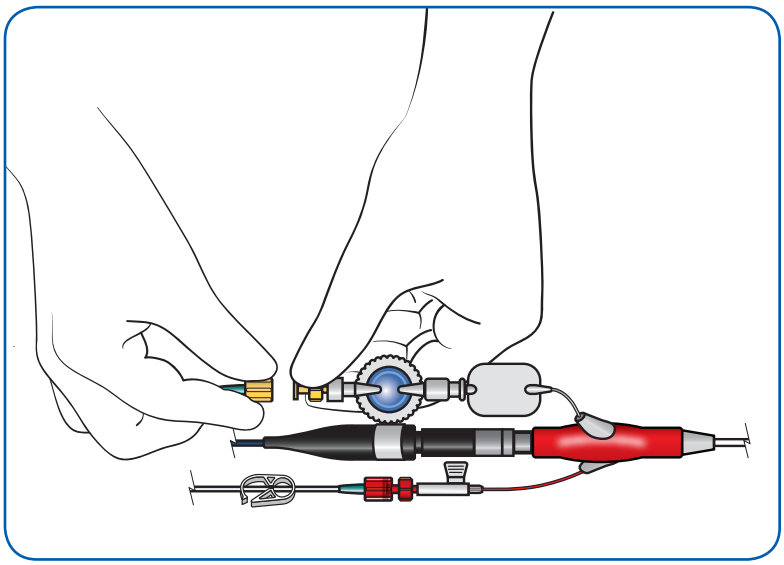


Figure 5.8 Connecting the Luer(s) to the Impella® Catheter

12. When the controller detects that the luer(s) are connected, it automatically begins priming the purge lumen at a bolus rate of greater than 250 mL/h and tracking the progress on the second progress bar.

13. Once the purge lumen is primed, the controller automatically advances to the next screen (Figure 5.9).

Figure 5.9 Priming the Placement Signal Lumen

14. Prime the Impella® Catheter placement signal lumen by squeezing the white flush valve for 10 seconds (see Figure 5.10) until the Automated Impella® Controller beeps. The progress bar shows the progress of the priming.

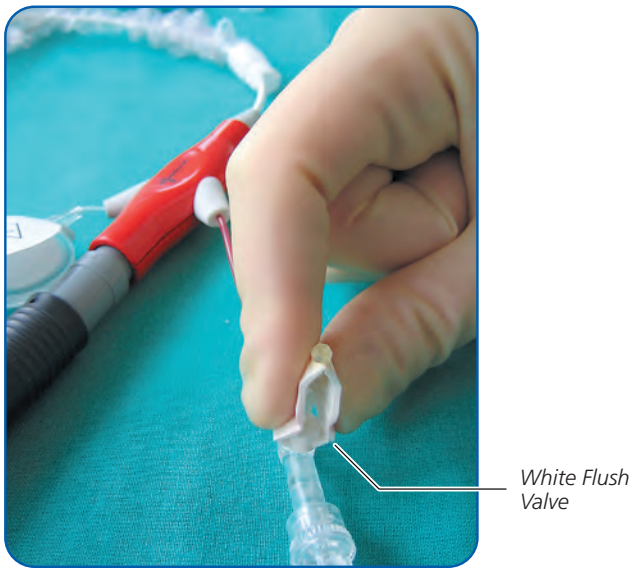


Figure 5.10 Squeezing the White Flush Valve to Prime the Placement Signal Lumen

15. When the system detects that the flush solution has reached the target pressure within the required amount of time, the system will advance to the next screen automatically.

16. The first step on the next screen prompts you to confirm that fluid is exiting the Impella® Catheter (see Figure 5.11).

ENTER PURGE FLUID DATA

1. After confirming that fluid is exiting the Impella® Catheter, enter the purge fluid information. The screen in Figure 5.11 shows a table of recommended default values for the purge fluid.

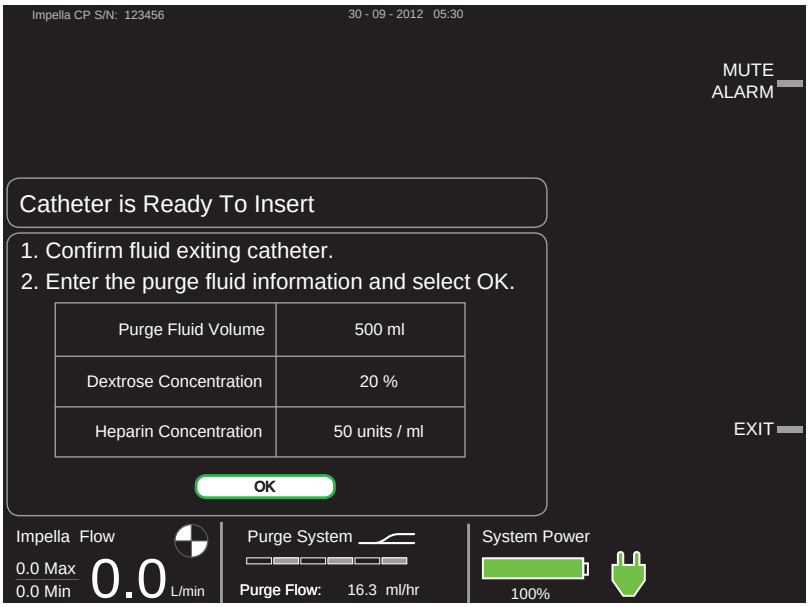


Figure 5.11 Entering Purge Fluid Information

2. To select the default values displayed on the screen, scroll to **OK** below the table and press the selector knob. This will select those values and automatically advance to the next screen.
3. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. The controller will use the default values if no other selections are made.
   - Purge fluid can be set to 50 mL, 100 mL, 250 mL, 500 mL (default), or 1000 mL.
   - Dextrose concentration can be set to 5%, 10%, 20% (default), 30%, or 40%.
   - Heparin concentration can be set to 0, 5, 10, 12.5, 15, 20, 25, or 50 units/mL (default).

SECURE THE PURGE TUBING

1. To complete the setup, connect the purge tubing to the white connector cable by pushing the purge tubing into the clips attached to the white connector cable as shown in Figure 5.12.

Figure 5.12 Connecting the Purge Tubing to the Connector Cable

IMPELLA® SYSTEM SET-UP CONFIGURATION

Figure 5.13 illustrates the correct set-up configuration of the Impella® System.

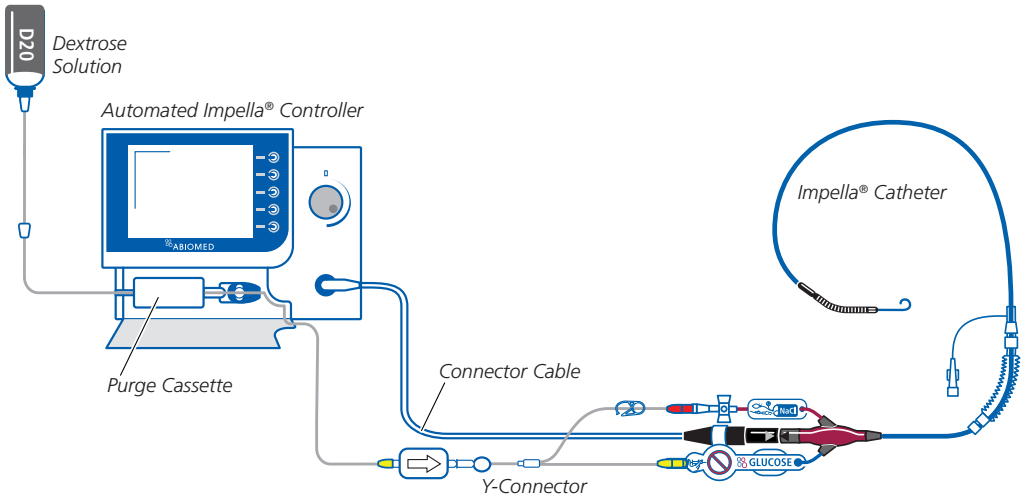


Figure 5.13 Set-up Configuration of the Impella® System

INSERTING THE IMPELLA® CATHETER

NOTE – Proper surgical procedures and techniques are the responsibility of the medical professional. The described procedure is furnished for information purposes only. Each physician must evaluate the appropriateness of the procedure based on his or her medical training and experience, the type of procedure, and the type of systems used.

Fluoroscopy is required to guide placement of the Impella® Catheter. The small placement guidewire must be reliably observed at all times.

Avoid manual compression of the inlet and outlet areas of the cannula assembly.

To prevent malfunction of the locking mechanism of the peel-away introducer, do ***NOT*** hold the hemostatic valve while inserting into the artery.

Do ***NOT*** kink or clamp the Impella® Catheter or the peel-away introducer.

Handle with care. The Impella® Catheter can be damaged during removal from packaging, preparation, insertion, and removal. Do ***NOT*** bend, pull, or place excess pressure on the catheter or mechanical components at any time.

1. Obtain access to the femoral artery.
2. Insert a 5–8 Fr introducer over the 0.035 guidewire (provided) to pre-dilate the vessel.
3. Remove the 5–8 Fr introducer over the 0.035 guidewire. Sequentially insert and remove the 8 Fr, 10 Fr, and 12 Fr dilators and then insert the peel-away introducer with dilator (see Figure 5.14). While inserting the introducer, hold the shaft of the introducer to slide it into the artery.

Figure 5.14 Inserting the Peel-Away Introducer

4. Administer heparin. When the ACT is greater than or equal to 250 seconds, remove the dilator.

Use Fluoroscopy for Placement

Impella® Catheter performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), portable C-Arm fluoroscopy, or chest x-ray can help confirm the position of the Impella® Catheter after placement, these methods do not allow visualization of the entire catheter assembly and are inadequate for reliably placing the Impella® Catheter across the aortic valve.

Introducer Setup

Refer to the instructions for use for each introducer for setup instructions.

When inserting the dilator, be sure to twist and lock it onto the hub of the sheath and twist it off when removing it from the sheath.

Keep ACT ≥250 Seconds

Achieving an ACT ≥ 250 seconds prior to removing the dilator will help prevent a thrombus from entering the catheter and causing a sudden stop on startup.

GP IIb-IIIa Inhibitors

If the patient is receiving a GP IIb-IIIa inhibitor, the dilator can be removed and the Impella® Catheter inserted when ACT is 200 or above.

5. Insert a diagnostic catheter (Abiomed recommends a 6 Fr AL1 or Multipurpose without side holes or 4–5 Fr pigtail with or without side holes) over a 0.035 inch diagnostic guidewire into the introducer and advance it into the left ventricle.

Figure 5.15 Inserting the Diagnostic Catheter

6. Remove the 0.035 inch diagnostic guidewire, leaving the diagnostic catheter in the ventricle. Form a curve or bend on the end of the 0.018 inch, 260 cm placement guidewire, following the instructions and heeding the precautions described in the sidebar box.

7. Advance the placement guidewire into the apex of the left ventricle.

8. Remove the diagnostic catheter.

To backload the catheter using the EasyGuide lumen

9. Insert the placement guidewire into the red EasyGuide lumen at the tip of the pigtail as shown in Figure 5.16. **(If the red EasyGuide lumen has been removed, follow the procedure outlined in step 10.)**

   a. Advance the guidewire until it exits the red lumen near the label.

   b. Remove the EasyGuide lumen by gently pulling the label in line with the catheter shaft while holding the Impella® Catheter as shown in Figure 5.16.

   c. If you suspect that a portion of the red lumen remains in the catheter, do NOT use the Impella® Catheter. Measure red lumen length using catheter markings (intact length is between 21.5 cm and 22.5 cm).

   d. Skip to step 11 if the catheter is successfully backloaded on the guidewire.

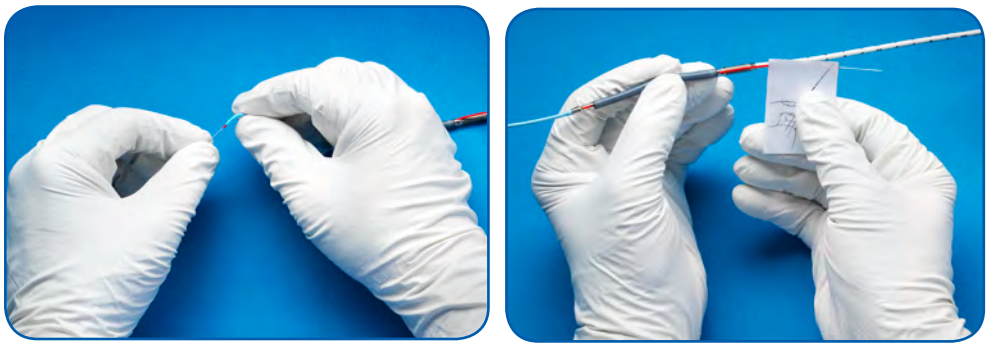


Figure 5.16 Loading the Catheter on the Guidewire using the EasyGuide Lumen

Using a Pigtail Diagnostic Catheter with Side Holes

When using a pigtail diagnostic catheter with side holes, ensure that the guidewire exits the end of the catheter and not the side hole. To do so, magnify the area one to two times as the guidewire begins to exit the pigtail.

Shaping the 0.018" Placement Guidewire

Place the shaping tool just distal to the weld separating the shaping ribbon from the body of the placement guidewire. Bend the shaping ribbon against the tool, using minimal force. Do NOT use a shaping tool with a sharp tip or edge. Do NOT pull the shaping tool along the length of the shaping ribbon as this could strip the coil off the guidewire and cause it to unfurl and separate. Inspect the coil and guidewire for damage after shaping and before using.

Do NOT reinsert the EasyGuide lumen

Once you remove the EasyGuide lumen from the Impella® Catheter, do not attempt to reinsert it. If necessary, follow instructions for backloading the catheter ***without*** *the EasyGuide lumen.*

To backload the catheter without the EasyGuide lumen

10. Wet the cannula with sterile water and backload the catheter onto the placement guidewire. One or two people can load the catheter on the guidewire.

One-person technique

a. Advance the guidewire into the Impella® Catheter and stabilize the cannula between the fingers as shown in Figure 5.17. This prevents pinching of the inlet area. The guidewire must exit the outlet area on the inner radius of the cannula and align with the straight black line on the catheter as shown in Figure 5.17. The cannula can be hyperextended as necessary to ensure the guidewire exits on the inner radius of the cannula.

Two-person technique

b. The scrub assistant can help stabilize the catheter by holding the catheter proximal to the motor. This will allow the implanting physician to visualize the inner radius. The guidewire must exit the outlet area on the inner radius of the cannula and align with the straight black line on the catheter, as shown in Figure 5.17. The physician can focus on advancing the guidewire and, if the cannula needs to be hyperextended, the scrub assistant is available to assist.

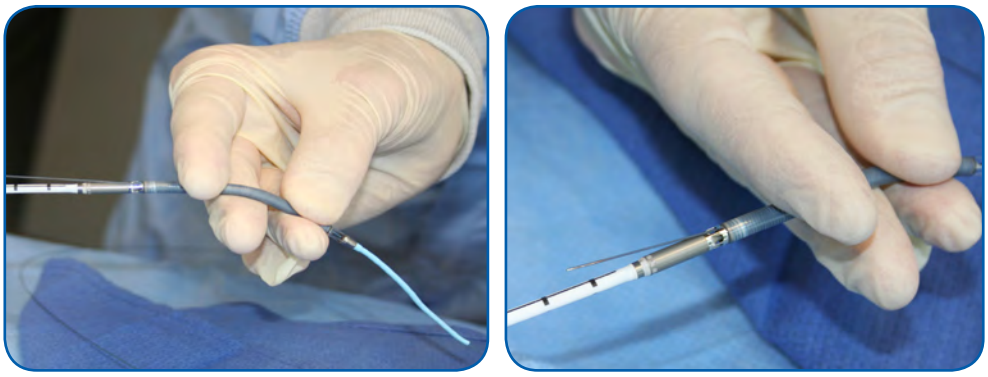


Figure 5.17 Loading the Catheter on the Guidewire without the EasyGuide Lumen and Aligning the Placement Guidewire

11. Advance the catheter through the hemostatic valve into the femoral artery (see Figure 5.18) and along the placement guidewire and across the aortic valve using a fixed-wire technique. Follow the catheter under fluoroscopy as it is advanced across the aortic valve, positioning the inlet area of the catheter 3.5 cm below the aortic valve annulus and in the middle of the ventricular chamber, free from the mitral valve chordae. Be careful not to coil the guidewire in the left ventricle.

Avoid Damaging Inlet Area

During placement of the Impella® Catheter, take care to avoid damage to the inlet area while holding the catheter and loading the placement guidewire.

Impella® Catheter Use in Open Heart Surgery

If the Impella® Catheter is used in the OR as part of open heart surgery, manipulation may be performed only at the access site. Direct manipulation of the catheter assembly through the aorta or ventricle may result in serious damage to the Impella® Catheter and serious injury to the patient.

Positioning in Small Hearts

If a patient has a smaller than normal ventricular cavity, the proper placement of the inlet area of the catheter may be 3 cm (rather than 3.5 cm) from the aortic valve.

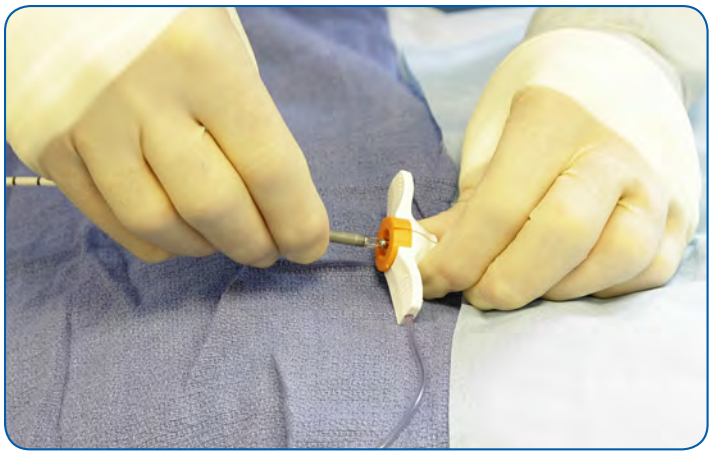


Figure 5.18 Inserting the Impella® Catheter

> To prevent device failure, do ***NOT*** start the Impella® Catheter until the guidewire has been removed.
>
> Do ***NOT*** remove the Impella® Catheter over the length of the guidewire.

12. Remove the placement guidewire.

13. Confirm position with fluoroscopy and confirm that an aortic waveform (see Figure 5.19) is displayed on the Automated Impella® Controller.

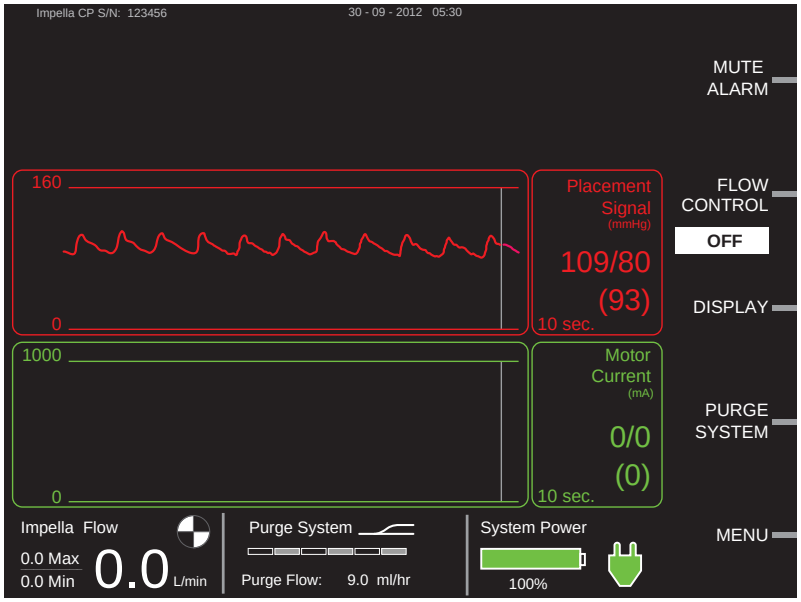


Figure 5.19 Aortic Waveform on Placement Screen

Take "Small Bites" During Insertion

While inserting the Impella® Catheter, push the catheter from only a few centimeters behind the hub of the peel-away introducer. This prevents the catheter from buckling during insertion.

Do NOT Touch Inlet or Outlet Areas

While feeding the Impella® Catheter through the introducer, hold the catheter at the cannula or motor housing. Do NOT touch the inlet or the outlet areas.

Maintaining ACT

After insertion of the catheter (and until explant), ACT should be maintained at 160 to 180 seconds.

Retrograde flow will occur across the aortic valve if the Impella® Catheter is set at P-level P-0.

1. Place the catheter plug at the same level as the patient's heart.
2. Reconfirm that the placement guidewire has been removed. Also reconfirm that the controller displays an aortic waveform (refer back to Figure 5.19) and the radiopaque marker band is located at the aortic valve. (See step 7 if the controller displays a ventricular waveform.)
3. Press the **FLOW CONTROL** soft button to open the menu. (see Figure 5.20). **Start Pump** is highlighted in blue. Press the selector knob to select **Start Pump** and the controller starts in AUTO, which automatically increases the flow rate over 30 seconds.

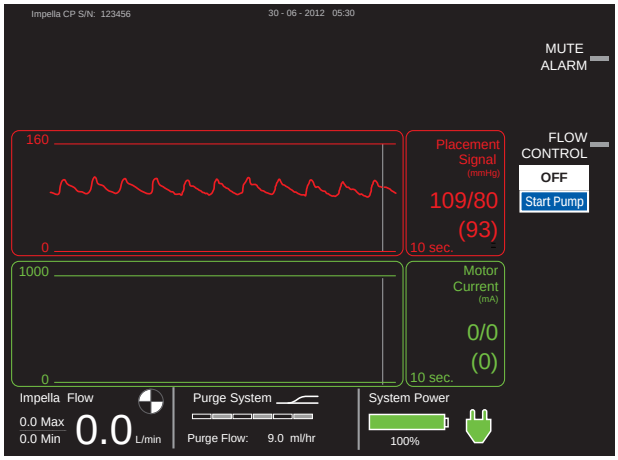


Figure 5.20 Starting the Impella CP® Catheter

4. Once the controller has begun to run in AUTO, pressing the **FLOW CONTROL** soft button again opens the FLOW CONTROL menu with options for **BOOST, AUTO**, and P-levels ranging from P-0 to P-8 as shown in Figure 5.21 and described in the "Modes of Operation" discussion that follows.

Figure 5.21 FLOW CONTROL Options for the Impella CP® Catheter

BOOST

The "BOOST" FLOW CONTROL setting maximizes the Impella® Catheter flow for 5 minutes. At the end of 5 minutes, the controller returns to the AUTO setting (or P-8 if previously running in P-level mode).

5. Wait 30 seconds for flow to reach its maximum value, then confirm correct and stable placement. Evaluate the catheter position in the aortic arch and remove any excess slack. The catheter should align against the lesser curvature of the aorta rather than the greater curvature. Verify placement with fluoroscopy and with the placement screen.
6. Reposition the catheter as necessary.
7. If the Impella® Catheter advances too far into the left ventricle and the controller displays a ventricular waveform (see Figure 5.22) rather than an aortic waveform, follow these steps to reposition the catheter.
   a. Pull the catheter back until an aortic waveform is present on the placement screen.
   b. When the aortic waveform is present, pull the catheter back an additional 4 cm. (The distance between adjacent markings on the catheter is 1 cm.) The catheter should now be positioned correctly.

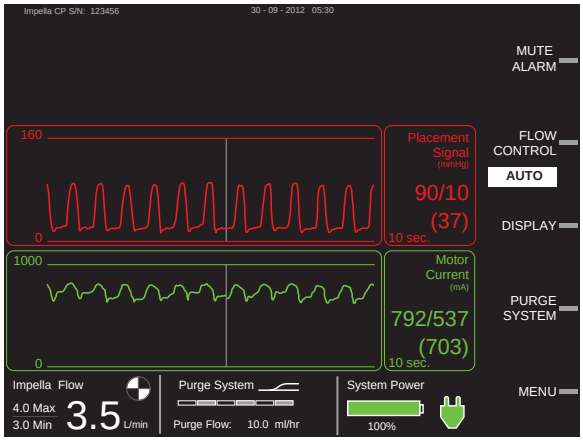


Figure 5.22 Ventricular Waveform on Placement Screen

MODES OF OPERATION

AUTO

In **AUTO**, the Automated Impella® Controller sets the motor speed of the Impella® Catheter to achieve the maximum possible flow without causing suction. After 3 hours of operation, if you have not transferred to the standard configuration, the controller automatically switches to P-level mode. Upon transfer from AUTO mode to P-level mode, the controller displays the message shown in Figure 5.23 and the AUTO setting is no longer an option.

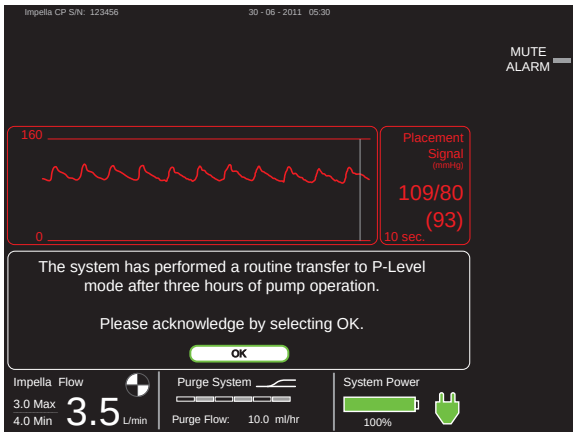


Figure 5.23 Transfer to P-level Mode

Check Positioning at Maximum Flow

When the flow rate is increased to maximum flow, the Impella® Catheter has a tendency to be drawn into the ventricle. Check positioning at maximum flow to ensure proper placement throughout the flow setting range.

Importance of Proper Impella® Catheter Placement

When the Impella® Catheter is not correctly placed, there is no effective unloading of the ventricle. The patient may not be benefiting from the flow rate shown on the controller.

Placement Monitoring Suspended

When the Impella® Catheter is operating in a low flow range, placement monitoring may be suspended and the flow rate in the lower left corner of the controller display screen will turn yellow to indicate that Impella position is unknown.

Reverse Flow

If the Impella® Catheter minimum flow is below 0.1 L/min then the controller will increase the motor speed to prevent reverse flow.

BOOST

If you select **BOOST**, the Automated Impella® Controller maximizes the Impella CP® Catheter flow for 5 minutes. At the end of 5 minutes, the controller returns to the AUTO setting (or P-8 if previously running in P-level mode).

P-LEVEL

In **P-LEVEL** mode you can select one of nine P-levels (P-0 to P-8) for the Impella® Catheter (see Table 5.2). Select the lowest P-level (P-2 or higher) that will enable you to achieve the flow rate necessary for patient support.

Table 5.2 P-level Flow Rates

P-level		*Flow Rate (L/min)	Revolutions Per Minute (rpm)
P-0	Impella® Catheter motor is stopped	0.0	0
P-1	Flow rate increases as the P-level increases	0.0 – 1.7	23,000
P-2		1.0 – 2.1	31,000
P-3		1.7 – 2.3	33,000
P-4		2.0 – 2.5	35,000
P-5		2.3 – 2.7	37,000
P-6		2.5 – 2.9	39,000
P-7		2.8 – 3.2	42,000
P-8	Recommended maximum P-level for continuous use	3.0 – 3.3	44,000
BOOST	Used to confirm stable position after placement; can be used to provide maximum flow for up to 5 minutes. After 5 minutes, the Automated Impella® Controller will automatically default to AUTO or P-8.	3.3 – 3.5	46,000

**Flow rate can vary due to suction or incorrect positioning.*

To operate the Impella® Catheter in P-level mode:

1. Press the **FLOW CONTROL** soft button to open the FLOW CONTROL menu.
2. Turn the selector knob to increase or decrease the flow rate.
3. Press the selector knob to select the new flow rate.

Automatic Switch to P-level Mode

After 3 hours of operation, if you have not transferred to the standard configuration, the Automated Impella® Controller automatically switches to P-level mode without the option to reselect AUTO mode.

Figure 5.24 Adjusting P-level

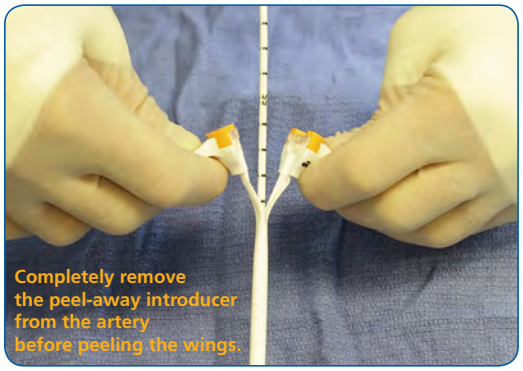
USE OF THE REPOSITIONING SHEATH AND THE PEEL-AWAY INTRODUCER

To prevent failure of the peel-away introducer, remove the peel-away introducer prior to transport when activated clotting time (ACT) is less than 150 seconds.

Be sure that the stopcock on the peel-away introducer or repositioning sheath is always kept in the closed position. Significant bleed back can result if the stopcock is open.

1. Flush the sidearm of the repositioning sheath located on the catheter shaft.

2. **Remove the peel-away introducer completely from the artery** over the catheter shaft to prevent trauma and significant bleeding and apply manual pressure above the puncture site.



3. Grasp the two "wings" and bend back until the valve assembly comes apart. Continue to peel the two wings until the introducer is completely separated from the catheter shaft (see Figure 5.25).

Figure 5.25 Removing the Peel-Away Introducer

4. Place a deadend cap on the sidearm of the repositioning sheath to prevent further usage. The sideport should not be used to give medication or draw blood because the blood could potentially clot. Pressure bags should not be connected to the sideport of the repositioning sheath. If a pressure bag is connected, the sideport must have an infusion pump or flow limiting valve in place to control the amount of fluid administered to the patient.

5. Slide the repositioning sheath over the catheter shaft and advance it into the artery to the blue suture pads.

6. Secure the repositioning unit to the patient with the blue suture pads or a StatLock® stabilization device.

7. Evaluate the catheter position in the aortic arch and remove any excess slack. The catheter should align against the lesser curvature of the aorta rather than the greater curvature. Verify placement with fluoroscopy and with the placement signal.

8. Attach the anticontamination sleeve to the blue section of the repositioning sheath. Lock the anchoring ring in place by turning it clockwise. Secure the catheter shaft in place by tightening the connected anchoring ring.

9. Carefully extend the anticontamination sleeve to maximum length and secure the end closest to the red Impella® plug by tightening the anchoring ring.

Maintaining ACT

After insertion of the catheter (and until explant), ACT should be maintained at 160 to 180 seconds.

Addition of Heparin to the Purge Solution

As soon as practical after catheter placement, change the purge fluid to include heparin. The recommended heparin concentration is 50 IU/mL in 20% dextrose solution. (Follow the Change Purge Fluid procedure described later in this section to change the purge fluid.)

TRANSFER TO STANDARD CONFIGURATION

Purge Pressure

When you transfer to the standard configuration, the purge pressure is no longer regulated at 600 mmHg. In the standard configuration, purge flow can range from 2 to 30 mL/hr and purge pressure can range from 300 to 1100 mmHg.

Handling Precaution

When connecting or disconnecting the red luer on the Y connector, do NOT grasp the white flush valve or apply force. Grasp the luer on both sides beneath the white flush valve while connecting or disconnecting lines from the red pressure sidearm.

Disconnecting the Y Connector

When you switch to the standard configuration, you can simply clamp, disconnect, and cap the red luer on the Y connector (as shown in Figure 5.26) or you can disconnect the Y connector entirely and connect the yellow luer on the purge tubing directly to the yellow check valve on the Impella® Catheter.

Abiomed recommends transitioning from the initial set-up configuration to the standard configuration as soon as practical. The standard configuration ensures that purge solution is delivered through the catheter to prevent blood from entering the motor. After 2 hours of operation, if the system is still in the set-up configuration, a white, advisory alarm notifies the operator to transfer to the standard configuration. Press Mute Alarm to silence the alarm for 30 minutes.

To transfer to the standard configuration, follow these steps.

1. Press **PURGE SYSTEM** and select "Transfer to Standard Configuration" from the menu.
2. Set up the sodium chloride (0.9% NaCl) infusion bag with pressure bag and a standard IV infusion set.
3. Clamp the red luer on the Y connector from the red pressure sidearm. Disconnect and end cap the red luer.
4. Create a slow drip from the NaCl pressure bag to flood the luer connector of the red pressure sidearm and make a wet-to-wet connection. Fully open the roller clamp. The controller may alarm during this step.
5. Select **OK** to confirm the transfer. You will no longer see the set-up icon on the bottom of the screen. The advisory alarm message will be gray.

Figure 5.26 illustrates the correct configuration of the Impella® System components after transitioning to the standard configuration from the set-up configuration.

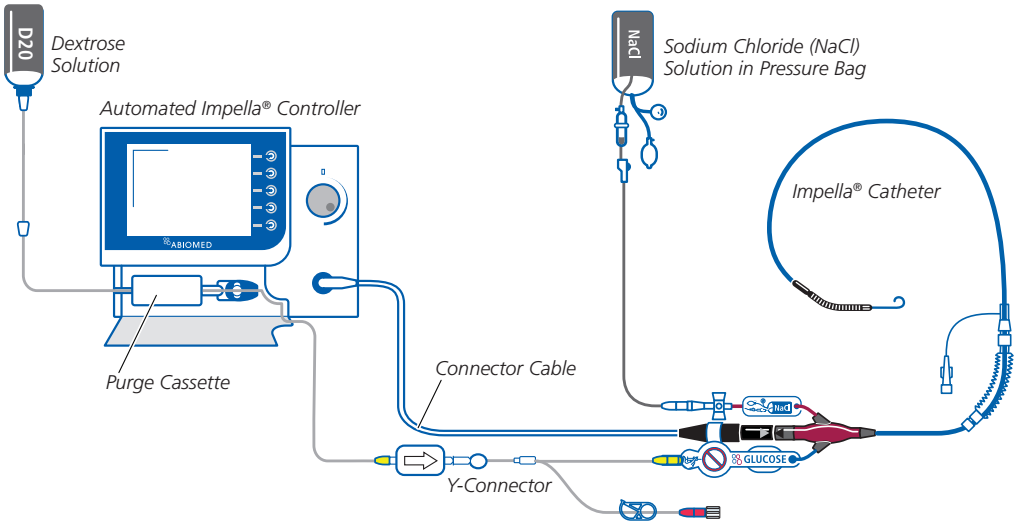


Figure 5.26 Standard Configuration for Impella® System after Transfer from the Set-up Configuration

Upon transfer to the standard configuration, the controller will switch to P-level mode and operate at P-8 if previously running in AUTO. If the controller was already in P-level mode at the time of the transfer, it will continue operating at the P-level at which it was operating at the time of the transfer. Once the controller is operating in the standard configuration, AUTO is no longer an option on the flow menu, as depicted in Figure 5.27.

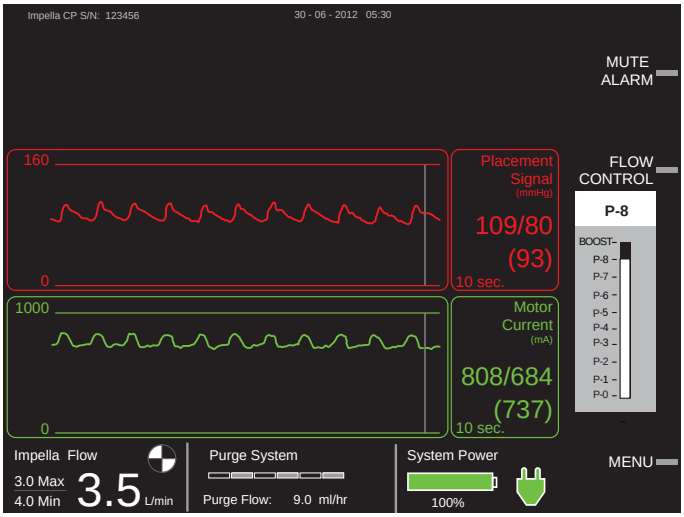


Figure 5.27 Flow Menu after Transfer to Standard Configuration

PURGE CASSETTE PROCEDURES

When replacing the purge cassette, the replacement process must be completed within 2 minutes. The Impella® Catheter may be damaged if replacement takes longer than 2 minutes.

There are five procedures for maintaining the Impella® Catheter purge system:

- Change purge system (changing cassette and purge fluid)
- Change purge fluid
- Change purge cassette
- De-air purge system
- Transfer to standard configuration

Each procedure can be accessed using the **PURGE SYSTEM** soft button. Transferring to the standard configuration was discussed above. The other four purge cassette procedures are discussed below.

CHANGE PURGE SYSTEM

Follow these steps to change both the purge cassette and purge fluid:

1. Press **PURGE SYSTEM** and select "Change Purge System" from the menu.

Replacement Time

If the purge flow is more than 7 mL/hr or the dextrose concentration is less than 20%, replacement time will be less than 2 minutes. Replacement should always be performed as quickly as possible.

2. Open the purge cassette package. If the system is in the standard configuration, disconnect the Y connector from the purge cassette tubing as shown in Figure 5.28.

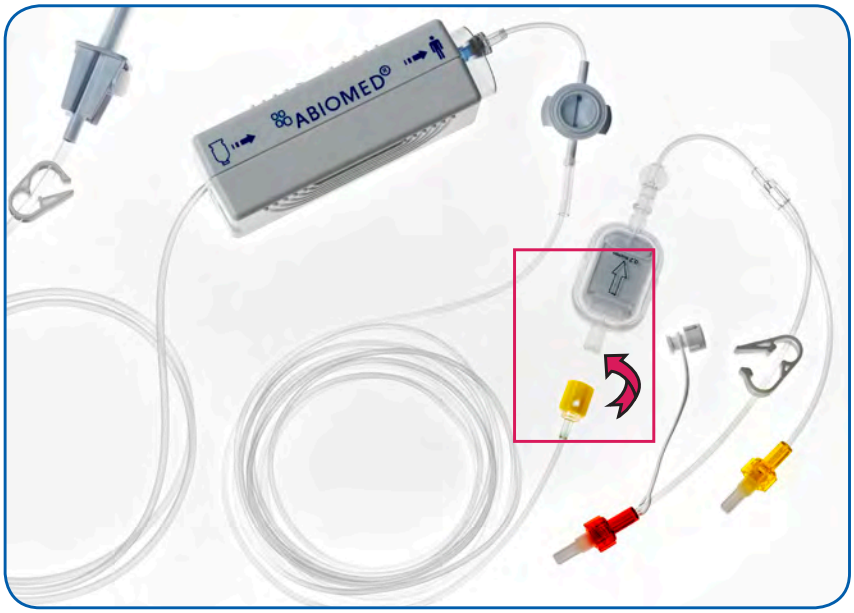


Figure 5.28 Disconnecting the Y Connector from the Purge Cassette Tubing

Connecting the Purge Tubing to the Catheter

If you have NOT switched to the standard configuration, be sure to connect both the red and yellow luers on the Y connector to the Impella® Catheter.

If you have switched to the standard configuration, connect the yellow luer on the purge tubing directly to the yellow check valve on the Impella® Catheter.

3. Spike the fluid bag/bottle.
4. Select **OK** to deliver a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
5. Disconnect the luer(s) from the Impella® Catheter and remove the used purge cassette.
6. Insert the new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge tubing through the gap in the purge cassette door when you close the door.
7. The system automatically primes the purge cassette. A progress bar shows the progress of the priming. Once the priming is complete, you are prompted to connect the purge tubing to the Impella® Catheter.
8. Connect the luer(s) on the end of the purge tubing to the luer(s) on the Impella® Catheter.
9. Purge system change is complete. Enter the purge fluid information and select **OK**.
   a. To select the default purge fluid values displayed on the screen, scroll to and select **OK**. This will select those values and automatically advance to the next screen.
   b. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. (Refer to "Entering Purge Fluid Data" in the Case Start discussion at the beginning of this section for a listing of purge fluid, dextrose concentration, and heparin concentration options.) The controller will use the default values if no other selections are made.

CHANGE PURGE FLUID

These are the steps you will follow to change only the purge fluid.

1. Press **PURGE SYSTEM** and select "Change Purge Fluid."
2. Select **OK** to deliver a bolus to the pressure reservoir so that the reservoir can maintain purge pressure during the change. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
3. Clamp the supply line before removing the purge fluid bag.
4. Replace the purge fluid bag and unclamp the supply line.
5. Select **OK** to complete bag change and start purge system again.
6. Enter the purge fluid information and select **OK**.
   a. To select the default purge fluid values displayed on the screen, scroll to and select **OK**. This will select those values and automatically advance to the next screen.
   b. To change the purge fluid information, scroll to the appropriate item and push the selector knob to select it. Then scroll through the values and push the selector knob to make a new selection. (Refer to "Entering Purge Fluid Data" in the Case Start discussion at the beginning of this section for a listing of purge fluid, dextrose concentration, and heparin concentration options.) The controller will use the default values if no other selections are made.
7. The next screen asks whether you want to flush the fluid from the purge cassette.
   a. To proceed with the flush, scroll to and select **OK**.
   b. To skip the flush, press **EXIT** to complete the Change Purge Fluid procedure.
8. If you are proceeding to flush the purge fluid from the cassette, select **OK** to deliver a bolus to the system. A progress bar shows the progress of the bolus. After the bolus is delivered, the controller automatically proceeds to the next screen.
9. Disconnect the luer(s) from the Impella® Catheter and select **OK** to flush the purge cassette. A progress bar shows the progress of the flush. When complete, the controller proceeds to the next screen.
10. When the purge cassette flush is complete you can connect the luer(s) to the Impella Catheter to complete the procedure or press **BACK** to repeat the flush.

Purge Solution Bottles

If the purge solution is supplied in bottles, open the vent on the purge fluid spike and follow the same procedure as if supplied in bags.

Flushing Purge Cassette Fluid

It may be helpful to flush the fluid from the purge cassette when you are changing dextrose concentration.

CHANGE PURGE CASSETTE

These are the steps you will follow to replace only the purge cassette.

1. Press **PURGE SYSTEM** and select "Change Purge Cassette."
2. Open the purge cassette package.
3. Disconnect the luer(s) from the Impella® Catheter and remove the used purge cassette.
4. Spike the fluid bag.
5. Insert a new purge cassette into the controller. Be sure to slide the purge pressure transmitter into place and extend the purge tubing through the gap in the purge cassette door when you close the door.

Changing the Purge Cassette

The Change Purge Cassette procedure will only be available if the Automated Impella® Controller detects that the cassette is defective, purge pressure is low, or the purge system is open.

6. The system automatically primes the purge cassette. A progress bar shows the progress of the priming. Once the priming is complete, you are prompted to connect the purge cassette to the Impella® Catheter.
7. Connect the luer(s) on the end of the purge tubing to the luer(s) on the Impella® Catheter.
8. When the purge cassette change is complete, press **OK** to exit.

DE-AIR PURGE SYSTEM

These are the steps you will follow to de-air the purge system.

1. Press **PURGE SYSTEM** and select "De-air Purge System."
2. Make sure that the purge fluid bag is NOT empty or inverted and that the tubing is NOT clamped.
3. Disconnect the purge tubing from the Impella® Catheter.
4. Press **OK** to initiate the de-air function. A progress bar shows the progress of the de-air procedure. Once complete, the system advances to the next screen.
5. Confirm that no air remains in the purge tubing. If air remains, press **BACK** to repeat the air removal process.
6. Connect the purge tubing to the luer(s) on the Impella® Catheter to complete the de-air procedure.

Purge Pressure

In the initial set-up configuration, the purge pressure is set to 600 mmHg, although it may not reach 600 mmHg in low resistance catheters in this configuration.

In the standard configuration, optimal purge pressure is different for every Impella® Catheter. Purge pressure can range from 300 mmHg to 1100 mmHg. While purge pressure varies during operation, the Automated Impella® Controller automatically maintains purge pressure within an acceptable range for each Impella® Catheter.

TROUBLESHOOTING THE PURGE SYSTEM

LOW PURGE PRESSURE

If at any time during the course of support with the Impella® Catheter, the Automated Impella® Controller alarms "Purge Pressure Low," follow the instructions below.

1. Inspect the purge system for leaks.
2. If there are no leaks, change to a purge fluid with a higher dextrose concentration. To do this, open the **PURGE SYSTEM** menu and select "Change Purge Fluid." Follow the instructions on the screen. (Refer to "Purge Cassette Procedures" earlier in this section of the manual.)
3. If the pressure stabilizes, no other action is required.
   If the purge pressure is not stable, proceed to Step 4.
4. If the low purge pressure alarm remains unresolved for more than 20 minutes, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to "Change Purge Cassette" instructions earlier in this section.)

5. If the low purge pressure alarm still remains unresolved for more than 20 minutes, this may be a sign of Impella® Catheter damage. Complete the following steps immediately:
   a. Open the **FLOW CONTROL** meter and reduce the P-level to P-2.
   b. Slowly pull back on the Impella® Catheter until it is in the descending aorta (approximately 20 cm for an average size patient; 1 cm marks are available on the catheter).
   c. Turn off the Impella® Catheter by opening the **FLOW CONTROL** meter and reducing the P-level to P-0.
   d. Disconnect the catheter from the Automated Impella® Controller.
   e. Remove the Impella® Catheter with the use of fluoroscopic imaging. If no fluoroscopy is available, leave the catheter in the descending aorta until fluoroscopy is available for visual assistance during removal of the Impella® Catheter.

PURGE SYSTEM OPEN

If at any time during the course of support with the Impella® Catheter, the Automated Impella® Controller alarms "Purge System Open," follow the instructions below.

1. Inspect the purge system for leaks.
2. If no leaks are visible, there may be a problem with the purge cassette. Replace the purge cassette. (Refer to instructions earlier in this section of the manual.)
3. If the Purge System Open alarm remains unresolved, this may be a sign of Impella® Catheter damage. Complete the following steps immediately:
   a. Open the **FLOW CONTROL** meter and reduce the P-level to P-2.
   b. Slowly pull back on the Impella® Catheter until it is in the descending aorta (approximately 20 cm for an average size patient; 1 cm marks are available on the catheter).
   c. Turn off the Impella® Catheter by opening the **FLOW CONTROL** meter and reducing the P-level to P-0.
   d. Disconnect the catheter from the Automated Impella® Controller.
   e. Remove the Impella® Catheter with the use of fluoroscopic imaging. If no fluoroscopy is available, leave the catheter in the descending aorta until fluoroscopy is available for visual assistance during removal of the Impella® Catheter.

Purge System Open Alarm

This alarm may occur if purge pressure is less than 100 mmHg.

Unresolved High Purge Pressure / Purge Flow Low Alarm

If not resolved by the recommendations provided, high purge pressure—which triggers the "Purge Flow Low" alarm message—could be an indication of a kink in the Impella® Catheter. In this case, the motor is no longer being purged and may eventually stop. Clinicians should monitor motor current and consider replacing the Impella® Catheter whenever a rise in motor current is seen.

HIGH PURGE PRESSURE

If the purge pressure exceeds 1100 mmHg, the Automated Impella® Controller displays the "Purge Flow Low" alarm message.

1. Inspect the purge system and check the Impella® Catheter for kinks in the tubing.
2. If pressure remains high, decrease the concentration of dextrose in the purge solution (eg, change from 20% dextrose to 10% dextrose).

De-air Procedure

You may run the de-air procedure (described earlier in this section) after changing the dextrose concentration to decrease the amount of time it takes for a change to occur.

PURGE SYSTEM BLOCKED

If a "Purge System Blocked" alarm occurs, the purge fluid flow stops.

1. Check the purge system tubing and the Impella® Catheter for kinks or blockages.
2. Decrease the concentration of dextrose in the purge solution.
3. Replace the purge cassette.

PATIENT WEANING

Weaning the patient from the Impella® Catheter is at the discretion of the physician.
The following weaning instructions are provided as guidance only.

1. To initiate weaning, press **FLOW CONTROL** and reduce P-level by 2 level increments over time intervals as cardiac function allows.
2. Keep Impella® Catheter P-level at P-2 or above until the catheter is ready to be explanted from the left ventricle.
3. When the patient's hemodynamics are stable, reduce the P-level to P-1 and pull the Impella® Catheter back across the aortic valve into the aorta.
4. If the patient's hemodynamics remain stable, follow instructions in the next section for removing the Impella® Catheter.

REMOVING THE IMPELLA® CATHETER

The Impella® Catheter can be removed after weaning when the introducer is still in place or when the catheter is secured with the repositioning sheath.

REMOVING THE IMPELLA® WITH THE INTRODUCER IN PLACE

1. Reduce the P-level to P-0.
2. Remove the Impella® Catheter through the introducer.
3. Wait until ACT drops below 150 seconds.
4. When ACT is below 150 seconds, remove the introducer.
5. Disconnect the connector cable from the Automated Impella® Controller and turn the controller off by pressing the power switch on the side of the controller for 3 seconds.
6. Apply manual compression for 40 minutes or per hospital protocol.

Remove the Impella® Catheter With Care

The Impella® Catheter must be removed with care to avoid damaging the catheter assembly.

REMOVING THE IMPELLA® SECURED WITH THE REPOSITIONING SHEATH

1. When ACT is below 150 seconds, press FLOW CONTROL and reduce the P-level to P-0.
2. Remove the Impella® Catheter and repositioning sheath together (the catheter will not come through the repositioning sheath).
3. Disconnect the connector cable from the Automated Impella® Controller and turn the controller off by pressing the power switch on the side of the controller for 3 seconds.
4. Apply manual compression for 40 minutes or per hospital protocol.

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PATIENT MANAGEMENT OVERVIEW

The information and instructions in this section of the manual are not intended to supersede established medical procedures concerning patient care. Best practice, as determined by the medical community, should always be observed. In each case, the clinician must determine whether the application of information provided is appropriate for the particular clinical setting.

Impella CP® and the Automated Impella® Controller

*The Impella CP® Catheter is designed for use with the Automated Impella® Controller and **cannot** be used with the Impella® Console.*

GENERAL PATIENT CARE CONSIDERATIONS

- Do not raise the head of the bed to higher than a 30-degree angle.
- Use knee immobilizer as needed to maintain access site straight.
- Access site management should be done in accordance with hospital protocol, using aseptic technique.
- Assess access site for bleeding and hematoma.
- Be careful not to pull on the Impella® Catheter when transferring a patient from one bed to another.
- To prevent the purge tubing from kinking, do not allow the red Impella® plug to hang freely from the catheter and do not bend the catheter near the red Impella® plug. Consider attaching the red Impella® plug and catheter to a short armboard to prevent the catheter from kinking near the plug.
- Use care when moving or turning a patient; the Impella® Catheter may move out of position and cause a positioning alarm.
- Monitor pedal pulses.

TRANSPORT WITHIN THE HOSPITAL

Patients supported with the Impella® System may require transport within the hospital for various reasons. Transport can be simple for patients supported with Impella® Catheter.

Considerations for transport within the hospital:

- The Automated Impella® Controller and Impella® Catheter are designed to operate on battery power for at least 1 hour.
- Confirm that the battery capacity displayed on the controller is 100%.
- If transport time might be longer than 1 hour, bring an extension cord or confirm you will be able to connect the controller to AC power once you arrive at your destination.
- When rolling the Automated Impella® Controller cart across a threshold, firmly grasp the cart handle and pull it over the threshold.
- Pay close attention to all system components and connections when rolling the Automated Impella® Controller cart over thresholds and through elevator doors.
- Do not stress the connector cable from the controller to the Impella® Catheter.

TRANSPORT BETWEEN HOSPITALS

During transport, the Automated Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Automated Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Automated Impella® Controller is no longer exposed to the disturbance.

GUIDELINES FOR PATIENT TRANSPORT

The Automated Impella® Controller and Impella® Catheter have been cleared by the FDA for hospital-to-hospital transport via ambulance, helicopter, or fixed-wing aircraft. To use the system during transport you must understand and follow the instructions in this manual. The transport team should include person(s) fully trained in the use of the Automated Impella® Controller and the Impella® Catheter.

Patients are placed on the Automated Impella® Controller for circulatory support for periods up to 6 hours. If, during this time, a patient requires additional resources and specialized teams at another location (eg, a larger facility such as a transplant center), the patient may be transferred to such a location using the Automated Impella® Controller.

Maintaining optimal patient hemodynamic status and correct Impella® Catheter position are two key factors in managing patients supported with the Impella® System during transport. Steps should be taken to eliminate or minimize any aspect of the transport that might adversely affect these factors.

The Automated Impella® Controller is designed to operate for 60 minutes on battery power. Transport teams should take this into consideration when planning the transport. If the total transport time is expected to include more than 60 minutes during which the system will be disconnected from AC power, arrangements should be made to use a vehicle with a built-in DC to AC power inverter.

IMPORTANT TRANSPORT CONSIDERATIONS

1. Planning is critical to success. Abiomed representatives can help with planning for transport. They can be contacted 24 hours a day at 1-800-422-8666.
2. The Automated Impella® Controller should be fully charged prior to transport. Keep the Automated Impella® Controller connected to AC power (or an AC inverter) whenever possible.
3. Do not stress the connector cable from the controller to the Impella® Catheter. Such tension could move the catheter out of correct position and compromise patient circulatory support.

4. Carefully monitor purge pressures during changes in altitude.
5. The Automated Impella® Controller should be positioned to allow easy access to the display screen and soft buttons to view alarms and make any necessary changes.
6. Maintain ACTs between 160 and 180 or at the level recommended by the physician responsible for the patient.

For more information about transport considerations, refer to "Patient Transport with the Automated Impella® Controller User Manual."

FAA ADVISORY

The Automated Impella® Controller has been subjected to, and passed, the EMC/EMI tests as specified in IEC 60601-1-2 (General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests). The Automated Impella® Controller does not, however, meet the requirements for conducted emissions of RTCA/DO-160G section 21.4 and has not been tested for radiated emissions per RTCA/DO-160G section 21.5. Abiomed recommends that air transport carriers follow the guidance FAA Advisory Circular AC No: 91-21.1B. Section 8-a of FAA Advisory Circular AC No: 91-21.1B states:

> "Equipment tested and found to exceed the section 21, Category M, emission levels are required to be evaluated in the operator's M-PED selected model aircraft for electromagnetic interference (EMI) and radio frequency interference (RFI). All navigation, communication, engine, and flight control systems will be operating in the selected aircraft during the evaluation."

RIGHT HEART FAILURE

The Impella CP® Catheter is a left-side support device only indicated for use for up to 6 hours. Patients being supported by the Impella CP® Catheter should be monitored for signs of right heart failure. Potential signs of right heart failure include:

- Reduced output from the Impella® Catheter
- Suction alarms
- Elevated filling pressures (CVP)
- Signs of liver failure
- Elevated pulmonary pressures

If the patient is exhibiting signs of right heart failure, the clinical team should assess the need for biventricular support.

Positioning and Placement

Impella® Catheter performance will be compromised if correct placement cannot be confirmed. While other imaging techniques, such as transesophageal echocardiography (TEE), portable C-Arm fluoroscopy, or chest x-ray, can help confirm the position of the Impella® Catheter after placement, these methods do not allow visualization of the entire catheter assembly and are inadequate for reliably placing the Impella® Catheter across the aortic valve.

ECG INTERFERENCE

Operating the Automated Impella® Controller may cause interference with electrocardiogram (ECG) signals. Please check the electrode pads and leads for good fixation and contact. If interference persists, activate the 50/100 Hz band-elimination filter or the 60/120 Hz band-elimination filter (also known as notch filter) on your ECG device. The filter frequency will be based on the AC power frequency for the country in which you are operating the equipment. If your ECG device does not have the appropriate filters, disconnect the Automated Impella® Controller temporarily from AC power to obtain an undisturbed signal. Please observe the battery status while running the Automated Impella® Controller on battery power.

LATEX

The Automated Impella® Controller, Impella® Catheter, and all accessories approved by Abiomed, are 100% latex free.

USE OF ECHOCARDIOGRAPHY FOR POSITIONING OF THE IMPELLA® CATHETER

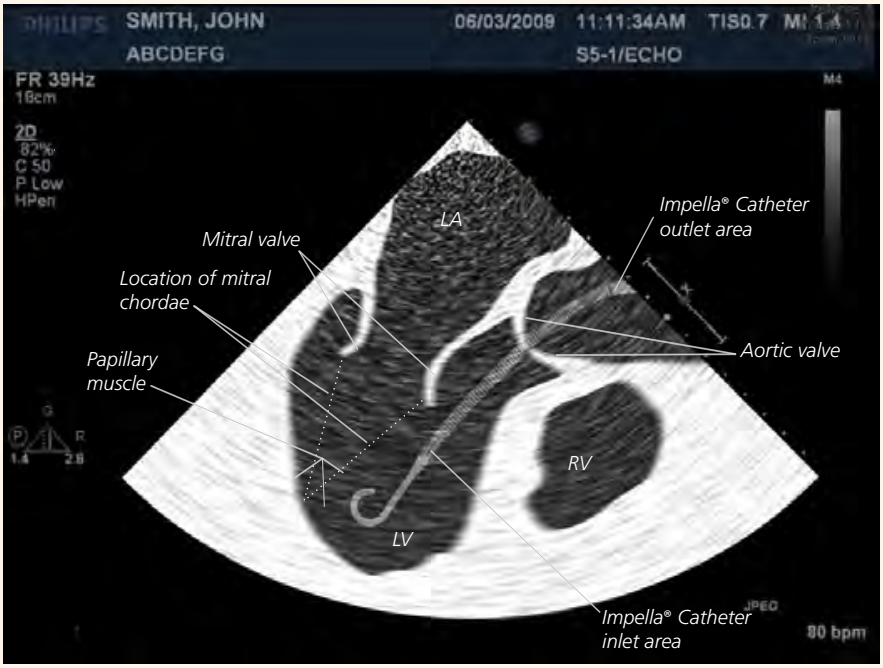
BACKGROUND

Echocardiography is a commonly used tool for evaluating the position of the Impella® Catheter relative to the aortic valve and other intraventricular structures post-placement. The best echocardiographic views for positioning the Impella® Catheter in the left ventricle are a long axis transesophageal echocardiogram (TEE) or a parasternal long axis transthoracic echocardiogram (TTE). These long axis views allow you to see both the aortic valve and Impella® Catheter inlet area.

Evaluate the position of the Impella® Catheter if the Automated Impella® Controller displays position alarms or if you observe lower than expected flows or signs of hemolysis. If the catheter does not appear to be correctly positioned, initiate steps to reposition it.

The illustrations on the following page identify the structures you would expect to see in transesophageal echocardiography (top) and transthoracic echocardiography (bottom). In these illustrations, the Impella® Catheter is positioned correctly; however, these depictions are stylized and in actual echocardiograms the pigtail and inlet and outlet areas may not be seen as distinctly.

Transesophageal Echocardiogram (TEE) of Impella® Catheter



Transthoracic Echocardiogram (TTE) of Impella® Catheter

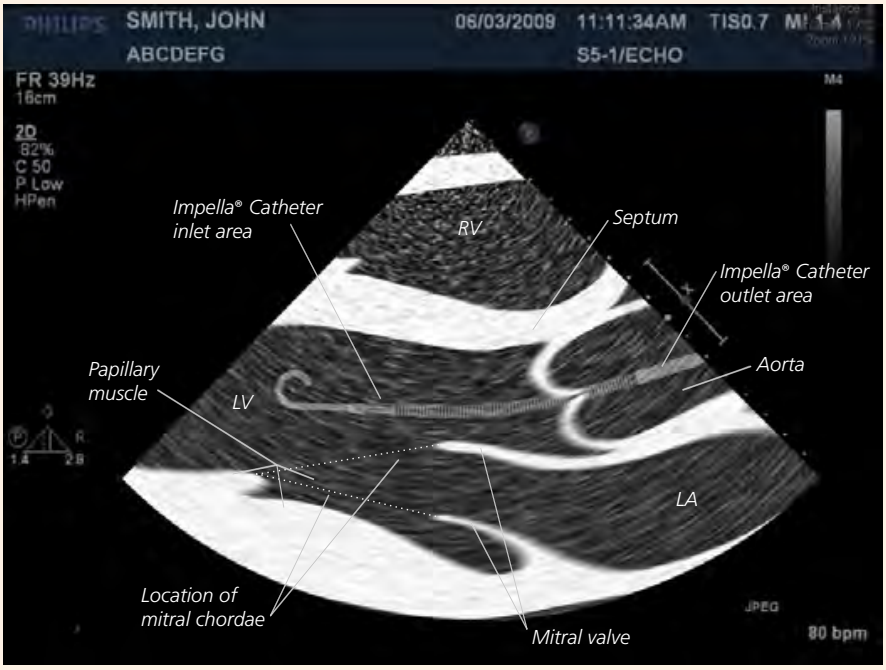


Figure 6.1 Labeled TEE and TTE Images of the Impella® Catheter Position

Four Impella® Catheter positions you are likely to encounter when examining echocardiograms from patients supported with the Impella® Catheter include:

- Correct Impella® Catheter position
- Impella® Catheter too far into the left ventricle
- Impella® Catheter inlet in the aorta
- Impella® Catheter in papillary muscle

The following pages describe each situation. Figure 6.2 illustrates a transesophageal echocardiogram (TEE) of each situation. Figure 6.3 illustrates a transthoracic echocardiogram (TTE) of each.

CORRECT IMPELLA® CATHETER POSITION

For optimal positioning of the Impella® Catheter, the inlet area of the catheter should be 3.5 cm below the aortic valve annulus and well away from papillary muscle and subannular structures. The outlet area should be well above the aortic valve. If the Impella® Catheter is correctly positioned, echocardiography will likely show the following, as depicted in Figures 6.2a (TEE) and 6.3a (TTE):

- Catheter inlet area 3.5 cm below the aortic valve
- Catheter outlet area well above the aortic valve (frequently not visible on TEE or TTE images)
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve

IMPELLA® CATHETER TOO FAR INTO THE LEFT VENTRICLE

If the Impella® Catheter is positioned too far into the left ventricle, the patient will not receive the benefit of Impella® Catheter support. Blood will enter the inlet area and exit the outlet area within the ventricle. Obstruction of the Impella® Catheter inlet area can lead to increased mechanical forces on blood cell walls and subsequent hemolysis, which often presents as dark or blood-colored urine. If the Impella® Catheter is too far into the left ventricle, echocardiography will likely show the following, as depicted in Figures 6.2b (TEE) and 6.3b (TTE):

- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve

IMPELLA® CATHETER INLET IN THE AORTA

If the inlet area of the Impella® Catheter is in the aorta, the patient will not receive the benefit of Impella® Catheter support. The catheter will pull blood from the aorta rather than the left ventricle. In addition, suction is possible if the inlet area is against the wall of the aorta or valve sinus. If the inlet area of the Impella® Catheter is in the aorta, echocardiography will likely show the following, as depicted in Figures 6.2c (TEE) and 6.3c (TTE):

- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve

IMPELLA® CATHETER IN PAPILLARY MUSCLE

If the inlet area of the Impella® Catheter is too close to or entangled in the papillary muscle and/or subannular structures surrounding the mitral valve, it can affect mitral valve function and negatively impact catheter flow. If the inlet area of the catheter is lodged adjacent to the papillary muscle, the inflow may be obstructed, resulting in suction alarms. This positioning is also likely to place the outlet area too close to the aortic valve, which can cause outflow at the level of the aortic valve with blood streaming back into the ventricle, resulting in turbulent flow and hemolysis. If the Impella® Catheter is too close to or entangled in the papillary muscle, echocardiography will likely show the following, as depicted in Figures 6.2d (TEE) and 6.3d (TTE):

- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

The following figures depict transesophageal and transthoracic echocardiographic images of these four Impella® Catheter positions. Figure 6.2 shows four transesophageal depictions of Impella® Catheter position and Figure 6.3 shows four transthoracic depictions of Impella® Catheter position.

a. Correct Impella® Catheter Position (TEE)

- Catheter inlet area 3.5 cm below the aortic valve
- Catheter outlet area well above the aortic valve
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve

b. Impella® Catheter Too Far into Left Ventricle (TEE)

- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve

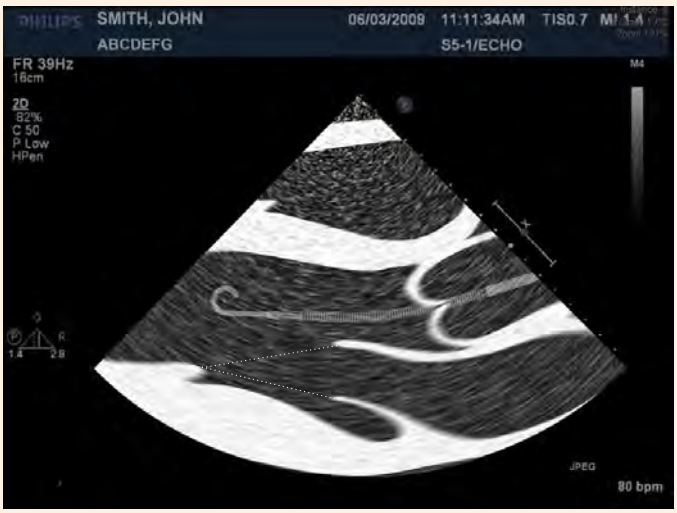
c. Impella® Catheter Inlet in Aorta (TEE)

- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve

d. Impella® Catheter in Papillary Muscle (TEE)

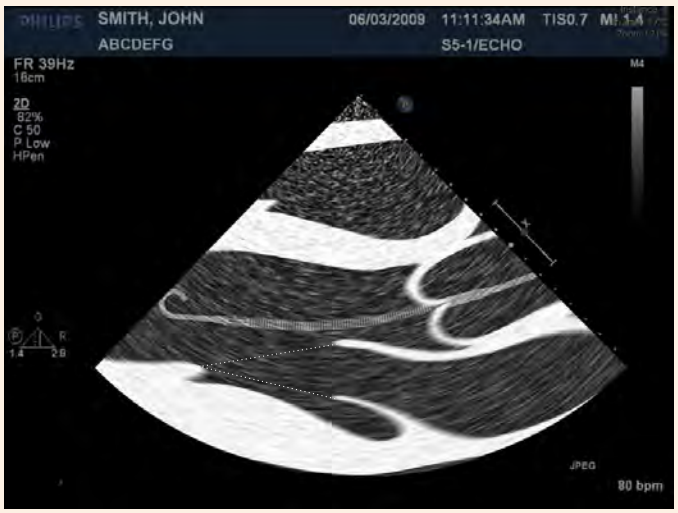
- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

Figure 6.2 Transesophageal Echocardiographic (TEE) Illustrations of Impella® Catheter Position



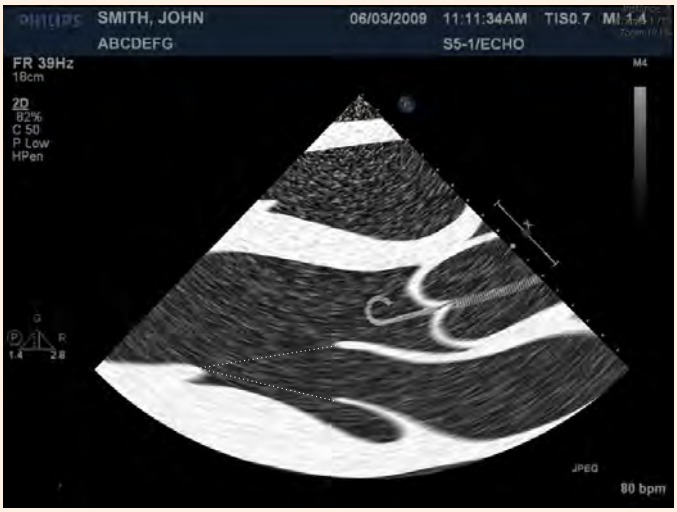
a. Correct Impella® Catheter Position (TTE)

- Catheter inlet area 3.5 cm below the aortic valve
- Catheter outlet area well above the aortic valve
- Catheter angled toward the left ventricular apex away from the heart wall and not curled up or blocking the mitral valve



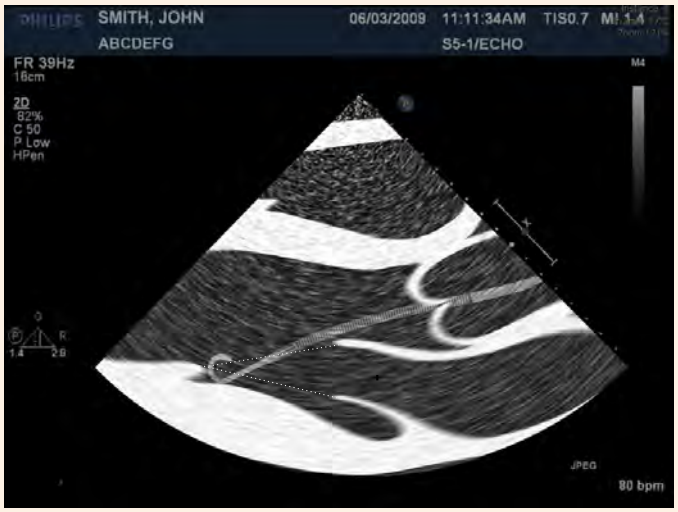
b. Impella® Catheter Too Far into Left Ventricle (TTE)

- Catheter inlet area more than 4 cm below the aortic valve
- Catheter outlet area across or near the aortic valve



c. Impella® Catheter Inlet in Aorta (TTE)

- Catheter inlet area in aorta or near the aortic valve
- Catheter pigtail too close to the mitral valve



d. Impella® Catheter in Papillary Muscle (TTE)

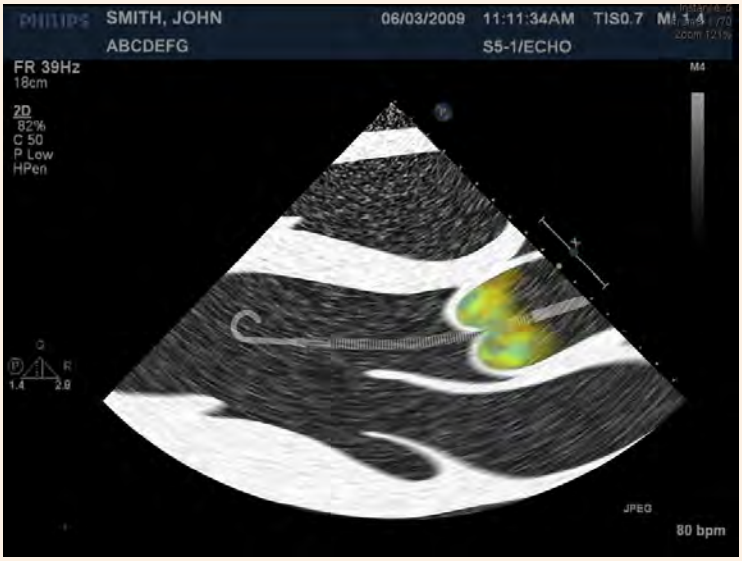
- Catheter pigtail in papillary muscle
- Catheter inlet area more than 4 cm below the aortic valve or lodged between papillary muscle and the myocardial wall
- Catheter outlet area too close to the aortic valve

Figure 6.3 Transthoracic Echocardiographic (TTE) Illustrations of Impella® Catheter Position

COLOR DOPPLER ECHOCARDIOGRAPHY

When moving a patient supported with an Impella® Catheter, it is important to monitor catheter migration. Adding color Doppler to an echo is another way to verify catheter position. If the Impella® Catheter is correctly positioned, a dense mosaic pattern of turbulence will appear *above* the aortic valve near the outlet area of the catheter, as shown in the top image in Figure 6.4. If, however, the echocardiogram reveals a dense mosaic pattern of turbulence *beneath* the aortic valve (bottom image in Figure 6.4), this likely indicates that the outlet area of the catheter is in the wrong position, that is, the catheter is too far into the ventricle or entangled in papillary muscle. (Note: If using transesophageal echocardiography [TEE], look for the mosaic patterns in the same locations relative to the aortic valve and Impella® Catheter outlet area.)

Correct Impella® Catheter Position (Color Doppler TTE)



Incorrect Impella® Catheter Position (Color Doppler TTE)

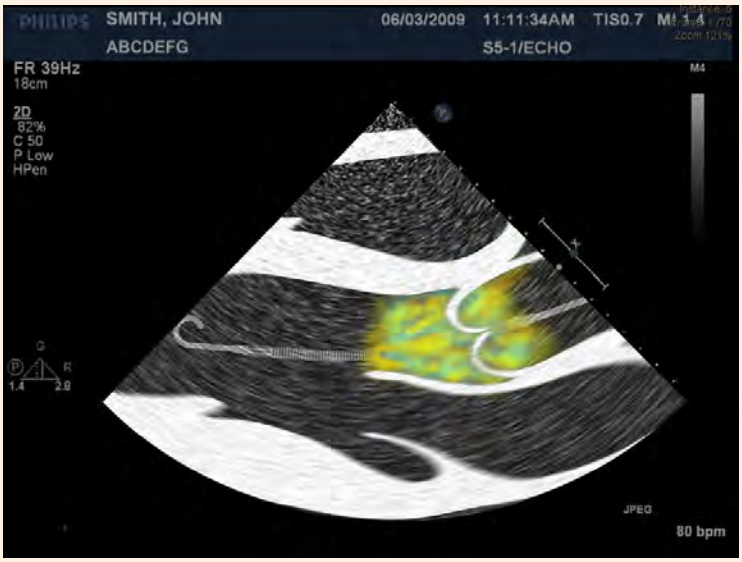


Figure 6.4 Correct and Incorrect Impella® Catheter Position (Color Doppler TTE)

POST-INSERTION POSITIONING (PIP) CHECKLIST

Completing the steps shown in the following post-insertion positioning checklist can help to ensure proper position of the Impella® Catheter following insertion. Pay particular attention to positioning after the patient is moved from the operating room or catheterization laboratory.

1. Remove slack in the Impella® Catheter by increasing P-level to AUTO or P-8 and align the catheter against the lesser curvature of the aorta (rather than the greater curvature).
2. Use fluoroscopy to verify that the slack has been removed.
3. Verify that the Impella® Catheter inlet area is optimally positioned 3.5 cm below the aortic valve.
4. Return to previous P-level.
5. Secure the Impella® Catheter at a firm external fixation point in the groin area.

Handling Repositioning Issues

To ensure that the Impella® Catheter remains positioned properly following insertion, discuss with the care team ***who*** *will resolve repositioning issues that may arise and* ***how*** *they will resolve the issues (eg, portable fluoroscopy, echocardiography).*

UNDERSTANDING AND MANAGING IMPELLA®CATHETER POSITION ALARMS

The Automated Impella® Controller continuously monitors the catheter based on the placement signal and the motor current.

- Placement signal: *Is the signal characteristic of aortic or ventricular pressure?*
- Motor current: *Is the signal "pulsatile" or "flattened"?*

If the system alarms with one of the positioning alarms described in this section, fluoroscopic imaging is the best method for confirming position. You can also use TEE, TTE, or a standard chest x-ray.

If the Impella® Catheter is either partly (just the pigtail) or completely in the ventricle, reposition the catheter under imaging guidance.

If the Impella® Catheter is completely out of the ventricle, do not attempt to reposition the catheter across the valve without a guidewire.

The following pages describe possible placement conditions and the associated signal characteristics and alarm messages as well as actions to take for each.

CORRECT POSITION

If the Impella® Catheter is in the correct position, the placement screen will appear as shown in Figure 6.5.

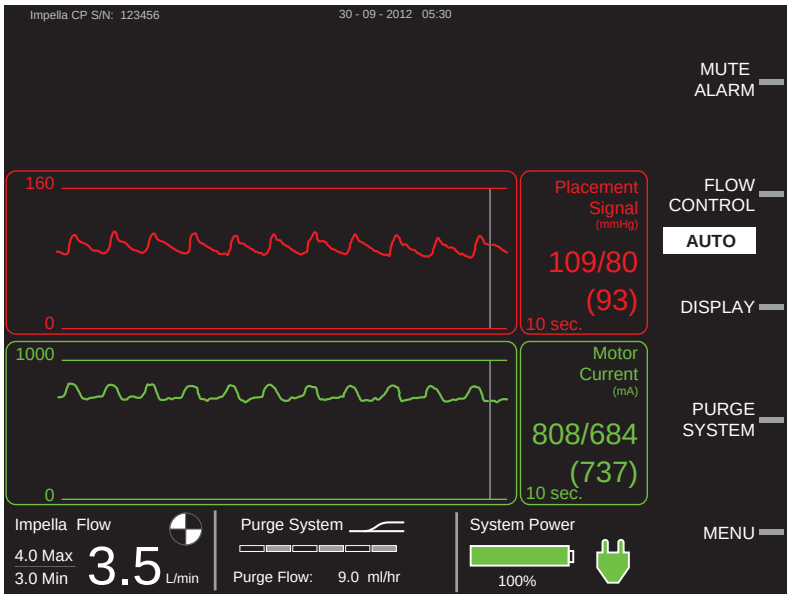


Figure 6.5 Correct Impella® Catheter Position

IMPELLA® CATHETER FULLY IN VENTRICLE

If the Impella® Catheter is fully in the ventricle, the following alarm will appear:

Impella Position In Ventricle

In this situation, the placement screen will appear as shown in Figure 6.6.

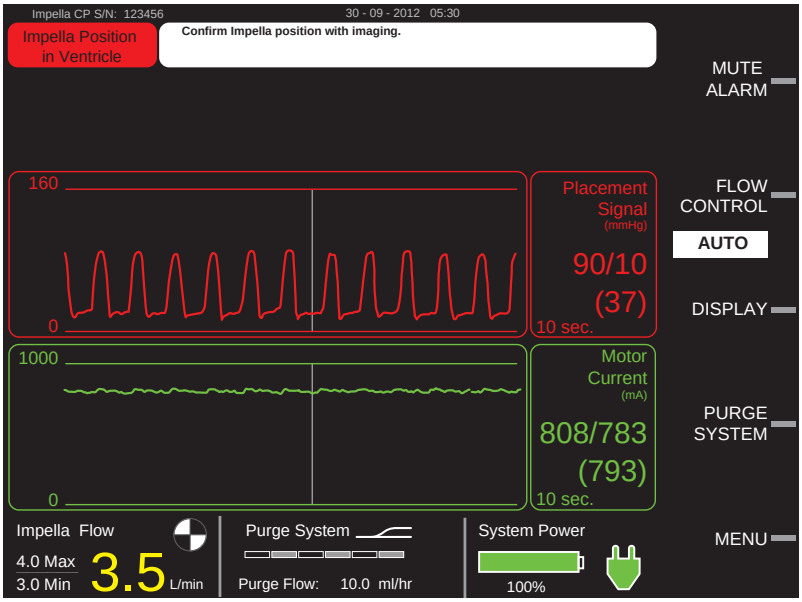


Figure 6.6 Impella® Catheter Fully in Ventricle

Yellow Flow Rate

If the Automated Impella® Controller detects incorrect or unknown catheter position, or if placement monitoring is suspended, the flow rate in the flow area appears in yellow as shown in Figure 6.6.

Actions to take:

1. Under fluoroscopic or echocardiographic guidance, if available, reduce the P-level to P-2 and carefully pull back the Impella® Catheter until the aortic waveform signal is showing.
2. When you see the aortic waveform signal, pull the catheter back an additional 4 cm.

IMPELLA® CATHETER COMPLETELY IN THE AORTA or INLET AND OUTLET AREAS IN VENTRICLE AND OPEN PRESSURE AREA IN AORTA

If the Impella® Catheter is completely in the aorta or if the inlet and outlet areas are in the ventricle and the open pressure area is in the aorta, the following alarm will appear:

Impella Position Wrong

In this situation, the placement screen will appear as shown in Figure 6.7.

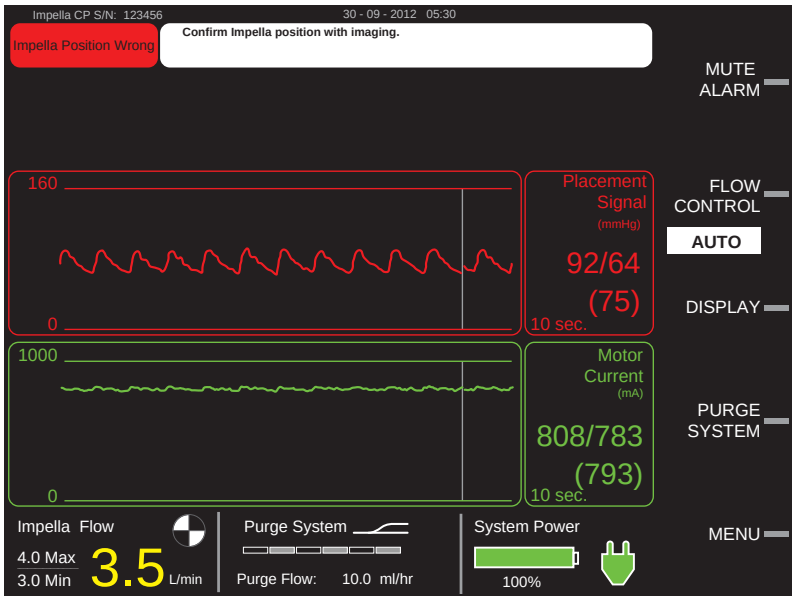


Figure 6.7 Impella® Catheter Completely in the Aorta or Inlet and Outlet Areas in Ventricle and Open Pressure Area in Aorta

Actions to take:

1. Under fluoroscopic or echocardiographic guidance, determine the Impella® Catheter position.
2. Reduce the P-level to P-2 and reposition the catheter as necessary.

LOW NATIVE HEART PULSATILITY

When a patient has poor native ventricular function, the placement signal may remain pulsatile; however, the amplitude will be dampened.

In a situation of low native heart pulsatility, the Automated Impella® Controller may not be able to determine the catheter position. You may see the following indication on the home screen:

Impella Position Unknown

In this situation, the screen will appear as shown in Figure 6.8.

Figure 6.8 Impella® Catheter Position Unknown

Actions to take:

1. Assess cardiac function.

IMPELLA® CATHETER OUTLET AREA ON OR NEAR AORTIC VALVE

If the Impella® Catheter outlet area is on or near the aortic valve, the catheter may be too deep in the ventricle. The following alarm will appear:

Impella Position Wrong

Actions to take:

1. Assess and adjust Impella® Catheter position under fluoroscopic or echocardiographic guidance, if available.
2. If fluoroscopic or echocardiographic guidance is not available, reduce the P-level to P-2 and gently pull the catheter back 2 cm to see if the condition resolves.

IMPELLA STOPPED

If the Impella® Catheter has stopped suddenly:

1. Try to restart the catheter at P-8.
2. If the Impella® does not restart at P-8, try to restart at P-2.
3. If the Impella® does not restart or stops again, wait 1 minute and try to restart again.
4. If the Impella® restarts, wean down to P-2 as the patient can tolerate. Under these circumstances, catheter function is not reliable and the Impella® may stop again.
5. If the Impella® does not restart, remove the Impella® from the ventricle as soon as possible to avoid aortic insufficiency.

SUCTION

Suction may occur if the blood volume available for the Impella® Catheter is inadequate or restricted. Suction limits the amount of support that the Impella® Catheter can provide to the patient and results in a decrease in arterial pressure and cardiac output. It can damage blood cells, leading to hemolysis. It may also be an indicator of right heart failure.

If the Automated Impella® Controller detects suction while running in AUTO mode, it automatically reduces motor speed to lower the flow rate to resolve the suction and displays the "Impella Flow Reduced" advisory alarm. If the suction is cleared, the controller returns the flow rate to the desired setting. If suction is still detected at the lowest motor speed, the controller displays the "Suction" alarm.

If the "Suction" or "Impella Flow Reduced" alarm occurs, follow the recommended actions:

1. Check the Impella® Catheter for correct positioning using imaging. Reposition the catheter by rotating or moving it into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the Impella® Catheter away from the interior ventricular wall.
2. Ensure patient has adequate volume.
3. Confirm right ventricular function by assessing CVP or right side function with echocardiography. If CVP is not an option, check the pulmonary artery diastolic pressure to assess the patient volume status.
4. Return P-level to pre-alarm setting.

If the Impella® Catheter has sudden low flows or suction at startup:

1. Remove the catheter from the patient and ensure that ACT is 250 seconds or above.
2. Closely inspect the inlet and outlet areas and remove any thrombus or other foreign materials.
3. If materials have been removed, run the Impella® at P-8 or AUTO in a basin.
4. If flows are still above 2.2 L/min, reinsert the Impella® Catheter into the patient.
5. If no material is visible or if the flows are still low, there could be a clot inside the device. An echo assessment of the left ventricle is recommended to rule out left ventricular thrombus before inserting another device.

HEMOLYSIS

When blood is pumped, it is subjected to mechanical forces. Depending on the strength of the blood cells and the amount of force applied, the cells may be damaged, allowing hemoglobin to enter the plasma. Pumping forces can be generated by a variety of medical procedures including heart lung bypass, hemodialysis, or ventricular assist device (VAD) support. Patient conditions—including catheter position, pre-existing medical conditions, and small left ventricular volumes—may also play a role in patient susceptibility to hemolysis.

Patients who develop high levels of hemolysis may show signs of decreased hemoglobin levels, dark or blood-colored urine, and in some cases, acute renal failure. Plasma-free hemoglobin (PfHgb) is the best indicator to confirm whether a patient is exposed to an unacceptable level of hemolysis.

Management technique may differ depending on the underlying cause of hemolysis. Table 6.1 provides guidance for various circumstances.

Table 6.1 Guide for Managing Hemolysis in Various Circumstances

Condition	Controller Indicators	Clinical Indicators	Management
Impella® inlet area in close proximity to intraventricular wall	• "Impella Flow Reduced" or "Suction" alarms • Lower than expected flows	Imaging (see note)	• Reposition the catheter by rotating or moving the catheter into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the catheter away from the intraventricular wall. • If repositioning will be delayed, reduce the P-level if tolerated by patient hemodynamics. Return to the previous P-level after repositioning. • Reassess position after flow rate has returned to desired target value.
Wrong pump position	• Position alarms with higher than expected flows • "Impella Flow Reduced" or "Suction" alarms with lower than expected flows • Pump outlet blocked alarms	Imaging (see note)	• Reposition the catheter by rotating or moving the catheter into or out of the ventricle slightly. Either or both of these actions could help move the inlet of the catheter away from the intraventricular wall. • If repositioning will be delayed, reduce the P-level if tolerated by patient hemodynamics. Return to the previous P-level after repositioning. • Reassess position after flow rate has returned to desired target value.
Higher than needed flow setting	• There may be no controller indicators • "Impella Flow Reduced" or "Suction" alarms	• Normal hemodynamics • Native recovery	• Reduce P-level until patient pressure starts to drop. • Slowly increase P-level.
Inadequate filling volume	• Position alarms • "Impella Flow Reduced" or "Suction" alarms • Lower than expected flows	• Low CVP • Low PCWP • Low AOP • High PA pressures • Right heart failure • High urine output • Increased bleeding or chest tube drainage	• Reduce the P-level if tolerated by patient hemodynamics. • Correct I and O balance. • Consider giving volume; additional volume will expand the end systolic ventricular volume. • Reduce PA pressure. • Improve right heart function.
Pre-existing patient conditions or other medical procedures	N/A	• Patient past medical history • Current procedures or treatments	

Note on imaging: *All imaging technology represents the anatomy in two dimensions (2D). It is not possible to assess the interactions between the catheter and the intraventricular anatomy that occur in three dimensions (3D). Abiomed strongly recommends that the catheter be repositioned, even if the imaging view shows correct position.*

OPERATING THE IMPELLA® CATHETER WITHOUT HEPARIN IN THE PURGE SOLUTION

The Impella® Catheter is designed to be operated with a purge solution that contains heparin. Operation of the system without heparin in the purge solution has not been tested. In the event that a patient is intolerant to heparin, due to heparin-induced thrombocytopenia (HIT) or bleeding, physicians should use their clinical judgment to assess the risks versus benefits of operating the Impella® System without heparin.

If it is in the best interest of the patient to operate the system without heparin, the dextrose solution is still required, and physicians should consider *systemic delivery* of an alternative anticoagulant. DO NOT add any alternative anticoagulant (such as a direct thrombin inhibitor) to the purge fluid. The Impella® Catheter has not been tested with any alternative anticoagulants in the purge solution.

PLACEMENT SIGNAL LUMEN

BACKGROUND

The Impella® Catheter uses a fluid-filled pressure lumen with an inlet at the proximal end of the motor housing and the pressure sensor located in the red Impella® plug. The Automated Impella® Controller software monitors both the pressure waveform characteristics and motor current to determine the placement of the Impella® Catheter inlet and outlet areas relative to the aortic valve.

Table 6.2 provides recommended standards for maintaining the placement signal.

Table 6.2 Recommended Standards for Maintenance of the Placement Signal

Periodic flushing of the placement signal lumen. Note: Either of these actions may result in sensor or position alarms.	*Slight dampening* If you observe a dampened placement signal, pinch the white flush valve located on the red sidearm for a few seconds to restore the placement signal quality. *Severe or lost pressure* 1. Close the roller clamp and disconnect the IV tubing connected to the red pressure sidearm. 2. Connect a syringe of saline to the port and squeeze the white flow valve as you draw negative pressure. 3. Continue aspiration of the port until blood is visualized in the syringe. 4. Disconnect the syringe and open the roller clamp until slow drips of saline exit the tubing. 5. Flood the open port of the red pressure sidearm and then reconnect. 6. Squeeze the white wings of the flow valve for 15 to 20 seconds to flush the pressure lumen to remove all blood from the pressure lumen.
Pressure bag inflation pressure	Maintain pressure bag inflation pressure between 300 mmHg and 350 mmHg.

Restoring Placement Signal Quality

You may get a sensor or position alarm if you pinch the white flush valve to restore placement signal quality.

FLUSH SOLUTION CHANGE OUT PROCEDURE

1. Prime the new NaCl flush solution setup and close the roller clamp.
2. Place the NaCl bag in a pressure bag and inflate to between 300 mmHg and 350 mmHg.
3. Close the roller clamp and disconnect the old flush solution connected at the red sidearm port.
4. Open the roller clamp on the new flush solution setup until you get a slow drip.
5. Position the male luer connector over the female luer connector and fill to overflow, displacing any air, as shown in Figure 6.9.

Figure 6.9 Displacing Air During Flush Solution Change Out Procedure

6. Connect and secure luer fittings.
7. Fully open the roller clamp and squeeze the white wings for approximately 5 to 10 seconds to complete the internal prime. This final prime should eliminate any risk of lost or dampened pressure caused by blood tracking into the pressure lumen during the pressure tubing change.

TIMED DATA RECORDING

The Automated Impella® Controller can hold up to 24 hours of real-time data. Once memory is full, the controller starts overwriting the old data. The timed data recording feature allows you to permanently save real-time operating data for later analysis. Timed data recording is automatically turned on during certain alarm conditions to capture data for analysis. You can also manually turn on the feature at any time to capture data for later analysis.

To manually access the timed data recording feature:

1. Press **MENU** and scroll to "Start Data Snapshot." Press the selector knob.
2. The controller records data for a predefined period of 10 minutes.

OPERATING THE IMPELLA® CATHETER IN ELECTROMAGNETIC FIELDS

The Impella® Catheter contains a permanent magnet motor that emits an electromagnetic field. This field may produce electromagnetic interference with other equipment. In addition, other equipment that emits a strong electromagnetic field may affect the operation of the Impella® Catheter motor.

ELECTROANATOMIC MAPPING (EAM) SYSTEMS

Examples of EAM Systems

CARTO® 3 System and CARTO® XP Navigation System (Biosense Webster, Inc.)

The electromagnetic field emitted by the Impella® Catheter may produce interference with the magnetic location detection component of the electroanatomic mapping (EAM) system, particularly when the mapping catheter is close to the Impella® Catheter motor. For example, mapping in the right or left ventricular outflow tracts places the mapping catheter in close proximity to the Impella® Catheter motor in the ascending aorta.

Electromagnetic interference may appear as:

- Instability in the displayed location of the mapping catheter
- Magnetic interference errors generated by the electroanatomic mapping system

When operating the Impella® Catheter in the presence of an EAM system, use P-level mode. Operate the Impella® Catheter at P-1–P-5 or P-7. The motor speeds at these P-levels cause the least interference. Best performance is observed when the Impella® Catheter motor is at least 3 cm from the sensors in the mapping catheter. If you suspect interference, follow the troubleshooting steps in Table 6.3.

Table 6.3 Troubleshooting When Operating the Impella® Catheter in the Presence of an EAM System

Observation	Actions
Interference with the magnetic location detection component of the EAM system	1. Check for and address other sources of interference. 2. Reposition the Impella® Catheter to ensure that the Impella® motor is at least 3 cm from the sensors in the mapping catheter; however do NOT pull the inlet area out of the left ventricle. 3. Ensure that the Impella® Catheter is operating at P-1–P-5 or P-7, as these P-levels cause the least interference.

MAGNETIC NAVIGATION SYSTEMS (MNS)

When initiating Impella® Catheter support in the presence of a magnetic navigation system (MNS), follow the steps below:

1. Insert the Impella® Catheter following the steps outlined in section 5 of this manual.
2. Place the MNS magnets in the "Reduced" or "Stowed" position.
3. Start the Impella® Catheter in the manner described in section 5 of this manual. Increase P-level to P-3.
4. Place the MNS magnets in the "Navigate" position and proceed with magnetic navigation.

Keep operating the Impella® Catheter at a P-level of at least P-3 when the MNS magnets are in the "Navigate" position. If the P-level falls below P-3, the Impella® Catheter may stop running. To resume operation, follow the steps in Table 6.4.

During magnetic navigation of the mapping catheter, the motor current of the Impella® Catheter may temporarily increase to the point that the catheter stops running. Table 6.4 explains how to resume operation.

When the MNS magnets are in the "Navigate" position, the displayed Impella® Catheter flow may be artificially elevated. To accurately assess the flow rate, note the displayed flow when the magnets are in the "Stowed" position.

Example of MNS

Stereotaxis Niobe® Magnetic Navigation System (Stereotaxis)

Table 6.4 Troubleshooting When Operating the Impella Catheter in the Presence of a MNS System

Observation	Actions
Unable to start Impella® or Impella® stops running	1. Place the MNS magnets in the "Reduced" position and attempt to start the Impella® Catheter. 2. If the Impella® Catheter does NOT start with the magnets in the "Reduced" position, place the magnets in the "Stowed" position and start the Impella® Catheter. 3. Increase the Impella® Catheter P-level to P-3 or higher. 4. Place the MNS magnets in the "Navigate" position and proceed with magnetic navigation.
MNS magnets: "Navigate" Displayed flow seems too high or MNS magnets: "Stowed" Displayed flow drops	The Impella® Catheter displayed flow will be artificially elevated when the MNS magnets are in the "Navigate" position. The displayed flow will be accurate when the MNS magnets are in the "Stowed" position.

TRANSFERRING FROM THE AUTOMATED IMPELLA® CONTROLLER TO A NEW AUTOMATED IMPELLA® CONTROLLER

Change Purge Fluid to Obtain Accurate Purge Values

To get accurate purge values after changing to a backup controller, perform the Change Purge Fluid procedure (described in section 5 of this manual) and replace the purge fluid bag.

TRANSFER STEPS

A backup Automated Impella® Controller should be available at all times when a patient is on support. In the event that the controller fails, follow the steps below to transition the Impella® Catheter to the backup controller.

1. Confirm that the backup controller is powered on and ready.
2. Press **PURGE SYSTEM** on the original controller, select Change Purge Fluid, and complete the step to bolus the purge system. (Do NOT flush the purge fluid from the cassette.)
3. Disconnect the yellow luer connector from the Impella® Catheter to release the pressure in the purge cassette.
4. Transfer the purge cassette and purge solution from the original controller to the backup controller.
5. Reconnect the yellow luer connector to the Impella® Catheter.
6. Remove the white connector cable from the original controller and plug it into the catheter plug on the front of the backup controller.
7. Once the Impella® Catheter is connected to the backup controller, wait for a message to appear on the screen asking you to confirm re-starting the Impella® Catheter at the previously set P-level.
8. Press **OK** within 10 seconds to confirm restarting the Impella® Catheter at the previously set P-level.
9. If the message to restart the Impella® Catheter does not appear within 30 seconds, restart the Impella® Catheter using the **FLOW CONTROL** soft button.

PATIENT MANAGEMENT CHECKLIST FOLLOWING TRANSFER OF SUPPORT

After transferring patient support to or from the Automated Impella® Controller, perform each of the following patient management checklist items:

1. Confirm Impella® Catheter placement using echocardiography.
2. Tighten the Tuohy-Borst valve (tighten all the way to the right) on the Impella® Catheter to prevent catheter migration.
3. Attach a saline pressure bag pressurized to 350 mmHg to the red sidearm and complete the "Transfer to Standard Configuration" procedure under the **PURGE SYSTEM** menu if not already completed.

Questions or Concerns?

Contact the local Abiomed team or call the 24 hour clinical support line at 1-800-422-8666.

EMERGENCY SHUTDOWN PROCEDURE

In the unlikely event that the Automated Impella® Controller software stops responding, follow the procedure below to restart the controller without stopping the Impella® Catheter.

1. Press and hold the power switch for 30 seconds.
2. An "Emergency Shutdown Imminent" alarm will sound at 15 seconds.
3. The controller will shut down after 30 seconds.
4. Restart the controller.

7 AUTOMATED IMPELLA® CONTROLLER ALARMS

ALARMS OVERVIEW 7.1

Alarm Levels 7.1

Alarm Display 7.2

Mute Alarm Function 7.2

ALARM MESSAGE SUMMARY 7.3

ALARMS OVERVIEW

The Automated Impella® Controller monitors various functions to determine whether specific operational parameters are within expected limits. When a parameter goes outside of its specified limits, the Automated Impella® Controller sounds an alarm tone and displays an alarm message that can be viewed on the display screen on the front of the controller. The alarm tone indicates the severity of the alarm. The alarm message on the display screen is color-coded for severity and provides details on the cause of the alarm and how to resolve the alarm. After muting an alarm, if another alarm occurs it will be displayed but only heard if it is a higher priority alarm than the one that was muted.

ALARM LEVELS

Alarms are divided into three levels of severity:

- Advisory (white)
- Serious (yellow)
- Critical (red)

Table 7.1 Alarm Levels

Category	Description	Audible Indicator*	Visual Indicator
Advisory	Notification	1 beep every 5 minutes	Alarm header on white background
Serious	May become harmful or life-threatening if not addressed immediately	3 beeps every 15 seconds	Alarm header on yellow background
Critical	Immediately harmful or life-threatening	10 beeps every 6.7 seconds	Alarm header on red background

* Sound pressure of audible alarm indicators is >80 dBA

For some alarms, there is a short delay between the triggered event and the audible annunciation and visual display of the alarm. (For more information, refer to the "Alarm Delay Information" discussion in section 8 of this manual.)

ALARM DISPLAY

The alarm window is located in the upper left region of the display screen on the front of the Automated Impella® Controller (see Figure 7.1). Alarms are listed in order of priority, with the highest priority alarm at the top. Up to three alarms may be displayed at one time. The colored background behind the highest priority alarm will alternate between two shades of that color. The white panel displayed to the right of the alarm header contains instructions for resolving the alarm condition. The instructions should be followed in the order given.

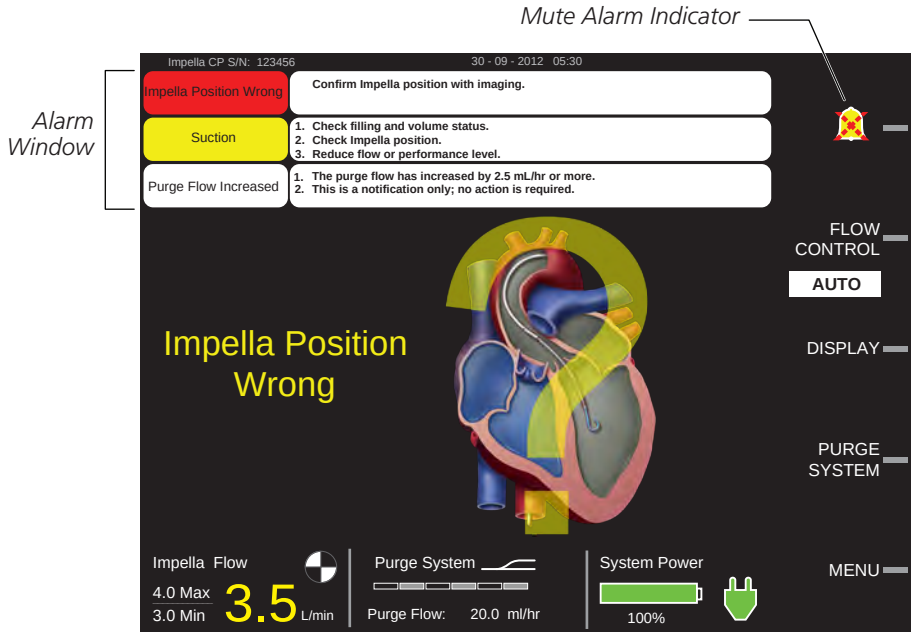


Figure 7.1 Alarm Window

Alarms That Resolve On Their Own

*The audible indicator will shut off if an alarm condition is resolved before you press **MUTE ALARM**. The visual message, however, will continue to be displayed, with the alarm header on a gray background, for 20 minutes or until you press **MUTE ALARM**. This allows you to identify the alarm that occurred.*

MUTE ALARM FUNCTION

Pressing the **MUTE ALARM** button on the upper right of the Automated Impella® Controller display screen will silence the audible alarm indicator for 2 minutes (for red or yellow alarms) or 5 minutes (for white advisory alarms). When an alarm is silenced, the words "MUTE ALARM" next to the button are replaced by the mute alarm indicator, a crossed-out bell icon (as shown in Figure 7.1).

ALARM HISTORY SCREEN

The alarm history screen may be accessed through the **MENU**. This screen contains a log of the alarms that occurred during the case. This log is not maintained when the Automated Impella® Controller is powered down or after a power failure. The controller does, however, maintain a long-term log that is saved after the Automated Impella® Controller is powered down or after a power failure and this information may be downloaded by Abiomed personnel.

ALARM MESSAGE SUMMARY

Table 7.2 briefly describes all of the alarm messages that may appear on the Automated Impella® Controller when used with the Impella CP® Catheter.

Table 7.2 Automated Impella® Controller Alarm Messages

Severity	Alarm Header	Action	Cause
Critical Alarms	**Air in Purge System**	The purge system has stopped. Initiate the De-air Tool and follow instructions to remove the air from the system.	There is air in the purge tubing.
	Battery Critically Low	Plug controller into AC power.	Battery power has 15% remaining capacity.
	Battery Failure	1. Plug controller into AC power. 2. Press switch located on the underside of the controller. 3. Switch to backup controller.	A battery switch is turned off or there is a malfunction of the switch.
	Battery Failure	Plug controller into AC power.	One of the batteries has failed.
	Battery Temperature High	Switch to backup controller.	Battery temperature is greater than 60°C.
	Complete Procedure	1. Follow the steps on the screen or 2. Exit the procedure	Complete Procedure serious alarm (yellow; *see next page*) is active and the user has not responded for an additional 2 minutes.
	Controller Failure	Switch to backup controller.	There is a problem with the controller electronics.
	Controller Failure	The purge system has stopped. Switch to backup controller.	The controller has detected a purge pressure sensor defect and has stopped the purge system.
	Emergency Shutdown Imminent	Release ON/OFF push button.	Power switch pressed for 15 seconds while Impella® is still connected.
	Impella Disconnected	1. Check cable connection to console. 2. Check Impella connection to cable.	Running Impella® Catheter disconnected.
	Impella Failure	Replace Impella.	There is a problem with the Impella® Catheter motor.
	Impella Position In Ventricle	Confirm Impella position with imaging.	Controller has detected that Impella® Catheter is fully in the ventricle.

Table 7.2 Automated Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Critical Alarms	**Impella Position Wrong**	Confirm Impella position with imaging.	Controller has detected that Impella® Catheter is in the wrong position.
	Impella Stopped	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt.	There may be a mechanical or electrical problem in the Impella® Catheter.
	Impella Stopped	1. Replace white connector cable. 2. Switch to backup controller. 3. Replace Impella Catheter.	There is a problem with the electronics.
	Impella Stopped **Controller Failure**	Switch to backup controller.	There is a problem with the controller electronics.
	Impella Stopped **Motor Current High**	1. Restart Impella. 2. Replace Impella after 3rd unsuccessful restart attempt.	There is a problem with the Impella® Catheter motor.
	Impella Stopped **Reverse Flow**	Restart Impella, or remove Impella from ventricle.	Impella® Catheter is not running; possible reverse flow through Impella® Catheter.
	Purge Flow Low	1. Check purge system tubing for kinks. 2. Decrease concentration of dextrose in the purge solution.	Purge pressure is ≥1100 mmHg with the purge flow <2 mL/hr.
	Purge Line Click-On Not Detected	Check the purge line click-on and make sure it is fully inserted.	The controller is not detecting that the purge pressure transmitter is clicked into the front of the controller.
	Purge Pressure Low	1. Check purge system tubing for leaks. 2. Increase concentration of dextrose in the purge solution. 3. Replace purge cassette.	Purge pressure has dropped below 300 mmHg with the purge flow ≥30 mL/hr for 30 seconds or longer.
	Purge System Failure	1. Replace purge cassette. 2. Switch to backup controller.	There is a problem with the purge cassette or purge unit driver.
	Purge System Open	1. Check the purge system tubing for open connections or leaks. 2. Replace purge cassette.	Purge pressure has dropped below 100 mmHg for 20 seconds or longer.

Table 7.2 Automated Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Critical Alarms	**Purge System Blocked**	1. Check all purge system tubing for kinks or blockages. 2. Decrease concentration of dextrose in the purge solution.	Purge flow has dropped below 1 mL/hr. Kinked or blocked purge connecting tube. Kinked or blocked purge lumen in Impella® Catheter.
	Reverse Flow	Check for high afterload pressure.	Reverse flow detected at high motor speed.
Serious Alarms	**Battery Comm. Failure**	Plug controller into AC power.	Loss of communication to the battery.
	Battery Level Low	Plug controller into AC power.	Battery has 50% remaining capacity.
	Battery Temperature High	1. Check controller for blocked air vents. 2. Switch to backup controller.	Battery temperature is greater than 50°C and less than or equal to 60°C.
	Complete Procedure	1. Follow the steps on the screen or 2. Exit the procedure	User has not responded to a de-air or purge procedure screen for more than 1 minute or a transfer to standard configuration screen for more than 5 minutes.
	Controller Error	Switch to backup controller.	There is a problem with the controller electronics.
	Impella Catheter Not Supported	1. Replace Impella with supported catheter (2.5, CP, 5.0, LD, RP). 2. Contact Abiomed Service to upgrade Impella Controller.	The Impella® Catheter is not supported to operate with the current version of controller software and/or hardware.
	Impella Defective	Do not use Impella. Replace Impella.	There is a problem with the Impella® Catheter electronics.
	Impella Flow Low	1. Check for suction. 2. Check for high afterload pressure.	Actual flow is below 2.5 L/min.
	Impella Outflow Blocked	1. Confirm Impella position with imaging. 2. Pull Impella back 2 cm.	Flow to Impella Catheter outlet area obstructed.
	Impella Position Wrong	1. Confirm Impella position with imaging. 2. Pull Impella back 2 cm.	Controller has detected that the Impella® Catheter is in the wrong position, with the outlet area too close to the aortic valve.

Table 7.2 Automated Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
Serious Alarms	**Impella Sensor Failure**	Placement Monitoring and Suction are suspended. 1. Monitor patient hemodynamics. 2. Monitor Impella position with imaging.	There is a problem with the Impella® Catheter sensor signal.
	Purge Cassette Failure	Replace purge cassette.	There is a problem with the purge cassette software.
	Purge Volume Critically Low	1. Open the **PURGE SYSTEM** menu and select Change Purge Fluid. 2. Follow the instructions to change the purge fluid.	There are 15 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.
	Suction	1. Check filling and volume status. 2. Check Impella position. 3. Reduce flow or P-level.	Suction is detected.
Advisory Alarms	**AC Power Disconnected**	Controller is running on battery power.	AC power was disconnected.
	Audio Off	The auditory signal for the following alarm has been disabled. *<Alarm will be listed here>*	User has disabled audio for Impella Sensor Failure, Purge Flow Low, or Purge System Blocked alarm.
	Impella Flow High	Check for high afterload pressure.	Reverse flow has been detected and minimum motor speed has been increased to more than target P-level.
	Impella Flow Reduced	1. Check Impella position. 2. Check left side filling and volume status. 3. Reduce flow setting.	Motor speed has been reduced in response to suction.
	Impella Position Unknown	Impella Catheter position unknown due to low pulsatility. Assess cardiac function.	Impella Catheter position unknown due to low pulsatility.
	Impella Position Unknown	Confirm Impella position with imaging.	Impella Catheter position unknown detected by algorithm

Table 7.2 Automated Impella® Controller Alarm Messages (continued)

Severity	Alarm Header	Action	Cause
	Placement Signal Lumen Blocked	Placement and Suction Monitoring are Suspended. Aspirate with syringe, then flush.	Controller detects placement signal pulsatility is low and speed and motor current are high for more than 5 consecutive minutes.
	Purge Cassette Incompatible	Contact Abiomed Service to update Impella Controller.	Incompatible purge cassette RFID version.
	Purge Flow Decreased	The purge flow has decreased by 2.5 mL/hr or more. This is a notification only; no action is required.	Purge flow has decreased by ≥2.5 mL/hr.
	Purge Flow Increased	The purge flow has increased by 2.5 mL/hr or more. This is a notification only; no action is required.	Purge flow has increased by ≥2.5 mL/hr.
	Purge Volume Low	1. Open **PURGE SYSTEM** menu and select Change Purge Fluid. 2. Follow the instructions to change the purge fluid.	There are 30 mL (in addition to 5% of the starting bag volume) or fewer remaining in the purge fluid bag.
	Transfer to Standard Configuration	Follow instructions under Purge System to transfer to Standard Configuration.	Follow instructions or press **MUTE ALARM** to clear the alarm for 30 minutes.

8 GENERAL SYSTEM INFORMATION

TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS 8.1

Terminology and Abbreviations 8.1

Symbols 8.1

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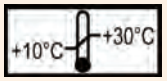
TERMINOLOGY, ABBREVIATIONS, AND SYMBOLS

TERMINOLOGY AND ABBREVIATIONS

Catheter serial number	Identification number of the Impella® Catheter; stated on the package label, on the red Impella® plug, and the Automated Impella® Controller display screen
Dextrose and **Glucose**	The terms "dextrose" and "glucose" are used interchangeably to refer to the solution used as purge fluid for the Impella® System
Hz	Hertz
Motor housing (or pump housing)	Enclosure of the Impella® Catheter motor
Pump	Central delivery unit of the Impella® Catheter, consisting of the motor, motor housing, cannula with inlet and outlet, and pigtail at the tip
Purge pressure	Pressure present in the Impella® Catheter and in the infusion line
Purge system	Impella® purge cassette used for rinsing the Impella® Catheter
Retrograde flow	Reverse flow through the cannula when the Impella® Catheter is at a standstill (eg, regurgitation)
V	Volt
VA	Volt ampere (Watt)

SYMBOLS

	Caution; consult instructions for use
	Defibrillator-proof type CF equipment
	Keep dry
	Storage temperature (eg, 10°C to 30°C)
CE	Declares conformity with Directive 93/42/EEC for medical devices, and with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
2011-02	Date of manufacture (eg, February 2011)

	Protect from sunlight
	Symbol for lot designation; the manufacturer's lot designation must be stated after the LOT symbol
REF 123456	Abiomed part number (eg, part number 123456)
SN 123456	Manufacturer's serial number (eg, serial number 123456)
Non Sterile!	The product is not sterile
2014-06	Use-by date (eg, use before June 2014)
	Do not reuse
	Sterilized using ethylene oxide
	Electric scrap; must be disposed of separately. Must not be disposed of as domestic waste.
	Protective Earth
	ON / OFF
	Alternating current (AC) only
	Equipotentiality
	Fuse
	Non-ionizing electromagnetic radiation
	USB port
	CAT 5 Port (Ethernet)

AUTOMATED IMPELLA® CONTROLLER MECHANICAL SPECIFICATIONS

Parameter	Specification	
Model Number	0048-0003-US	
Temperature	Operating:	10°C to 40°C (50°F to 104°F)
	Storage:	–15°C to 50°C (5°F to 122°F)
Relative Humidity	Operating:	95%
	Storage:	95%
Atmospheric Pressure	Operating:	8000 ft (750 hPa) to –1000 ft (1050 hPa)
	Storage:	18,000 ft (500 hPa) to –1000 ft (1050 hPa)
Dimensions	Height:	351 mm (13.8 in)
	Width:	443 mm (17.4 in)
	Depth:	236 mm (9.3 in)
Dimensions – Packaged	Height:	508 mm (20.0 in)
	Width:	559 mm (22.0 in)
	Depth:	406 mm (15.0 in)
Weight	Maximum:	11.8 kg (26.1 lbs)
Weight – Packaged	Maximum:	13.6 kg (30 lbs)
Maintenance and repair interval	12 months (Work must be performed by technicians authorized by Abiomed who have completed Abiomed's Service Training Certification Program)	

AUTOMATED IMPELLA® CONTROLLER ELECTRICAL SPECIFICATIONS

AC operation	100-230 V AC (nominal); 47-63 Hz; 1.1 A
Internal battery operation	14.4 V DC (nominal); lithium ion
Characteristic values	
Max. power consumption under load	120 VA
9.7 fuses	2 Amp. 250 V. 5 mm x 20 mm, slow-blow fuses
Running time without AC power with fully charged batteries	At least 60 minutes (charging duration of at least 5 hours)
Electrical system	Installation in accordance with pertinent regulations is required for use in medical facilities (eg, VDE 0100, VDE 0107, or ICE stipulations). Observe country-specific regulations and national deviations.

NOTE: Circuit diagrams available upon request.

EQUIPMENT DESIGN

The Automated Impella® Controller conforms to the applicable requirements of the following standards:

- IEC 60601-1 (2005/01/01) Ed:3 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- CSA C22.2#60601-1 (2008) Ed:3 *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- CENELEC EN60601-1 (2006) *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.* Included when concurrent with IEC 60601
- AAMI ES60601-1 (2005) *Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance*
- UL 60601-1 (2003), +Revision (2006) 1st Edition *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- CAN/CSA C22.2 No 601.1-M90 (1990; Reaffirmed 2005) + Amendment 2 (2006), *Medical Electrical Equipment, Part 1: General Requirements for Safety*
- IEC 60601-1 (1998) 2nd Edition *Medical Electrical Equipment Part 1: General Requirements for Safety* + (Amd. 1-1991) (CENELEC EN 60601-1: 1990) + (Amd. 2-1995) (Corrigendum-1995)
- IEC 60601-1-1 (2000), 2nd Edition *Medical Electrical Equipment, Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Equipment*
- IEC 60601-1-4 (2000), Edition 1.1 Consolidated Edition, *Medical Electrical Equipment Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems*
- IEC 60601-1-2:2007 Edition 3, *Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- IEC 60601-1-2 (2001), *Medical Electrical Equipment, Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*
- IEC 60601-1-6 (2010) 3rd Edition *Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability*
- IEC 60601-1-6 (2004) *Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability*
- IEC 60601-1-8 (2006) 2nd Edition *Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*
- IEC 60601-1-8 (2003) *Medical Electrical Equipment – Part 1-8: General Requirements for Safety – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems*

EQUIPMENT CLASSIFICATIONS

Type of protection against electric shock	IEC 60601-1: Class I degree of protection: CF defibrillation-proof and internally powered. Relies not only on basic insulation against shock but also includes additional protection. Accomplished by providing means for connecting the equipment to the protective earth conductor of the fixed wiring of the installation in a way that prevents accessible metal parts from becoming live if basic insulation fails.
Degree of protection against electric shock for Automated Impella® Controller	Class I Equipment
Mode of operation	Continuous
Degree of protection against explosion hazard	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Also not suitable for use in an oxygen-enriched atmosphere.
Degree of protection against harmful ingress of water	IEC 60529: IPX1 protected against dripping water.

FEDERAL COMMUNICATIONS COMMISSION (FCC) NOTICE

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Abiomed, Inc. could void the user's authority to operate this device.

ELECTROMAGNETIC COMPATIBILITY

	Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the electromagnetic compatibility (EMC) information provided in this document.
	Portable and mobile RF communications equipment can affect medical electrical equipment.
	The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
	Use of cables, other than those sold by Abiomed, may result in increased emissions or decreased immunity of the Automated Impella® Controller.
	The Automated Impella® Controller uses RFID (radio frequency identification) to identify and communicate with the purge cassette. Other equipment may interfere with the Automated Impella® Controller even if that other equipment complies with CISPR emission requirements.
	During transport, the Automated Impella® Controller may be exposed to stronger electromagnetic disturbance than during in-hospital use. Strong electromagnetic disturbance may cause the Automated Impella® Controller to display soft button menu selections that were not selected by the user. Operators should be aware that, under these conditions, the operating parameters are not affected. No user intervention is required. Monitor Impella® Catheter flow and patient hemodynamics to confirm normal operation. The condition will resolve itself once the Automated Impella® Controller is no longer exposed to the disturbance.

NOTE: The EMC tables and other guidelines that are included in this manual provide information to the customer or user that is essential in determining the suitability of the equipment or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use permit the equipment or system to perform to its intended use without disturbing other equipment and systems or non-medical electrical equipment.

TABLE 201
Guidance and Manufacturer's Declaration – Emissions, All Equipment and Systems

The Automated Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Automated Impella® Controller should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enforcement – Guidance
RF Emissions CISPR 11	Group 1 Class A	The Automated Impella® Controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Class A	The Automated Impella® Controller is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Flicker IEC 61000-3-3	Complies	

TABLE 202
Guidance and Manufacturer's Declaration – Immunity

The Automated Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Automated Impella® Controller should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	±2 kV Mains ±1 kV for input/ output lines	±2 kV Mains ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	> 95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles > 95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Automated Impella® Controller requires continued operation during power mains interruptions, it is recommended that the Automated Impella® Controller be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

TABLE 203

Guidance and Manufacturer's Declaration – Emissions, Equipment and Systems that are Life-Supporting

The Automated Impella® Controller is intended for use in the electromagnetic environment specified below. The customer or user of the Automated Impella® Controller should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be separated from the Automated Impella® Controller by no less than the recommended separation distances calculated/listed below:
Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz	10 Vrms	$d = 0.35\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.6\sqrt{P}$ 80 to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Automated Impella® Controller is used exceeds the applicable RF compliance level above, the Automated Impella® Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Automated Impella® Controller.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m

TABLE 205

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Automated Impella® Controller, Equipment and Systems that are Life-Supporting

The Automated Impella® Controller is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Automated Impella® Controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Automated Impella® Controller as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output	Recommended Separation Distances for the Automated Impella® Controller (m)		
Output Power of Transmitter (Watts)	150 KHz to 80 MHz $d = 0.35\sqrt{P}$	80 to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
0.01	0.04	0.06	0.12
0.1	0.11	0.19	0.38
1	0.35	0.6	1.2
10	1.11	1.9	3.8
100	3.5	6.0	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

RFID Transmitter / Receiver Specifications	
Frequency	13.56 MHz
Receiver bandwidth	14 kHz
Effective radiated power	30 nW
Modulation	ASK

SLAVE MONITOR CONNECTION

If equipped with a VGA connector, the Automated Impella® Controller can be connected to a monitor to display the information from the controller to another screen at a resolution of 800 x 600 pixels. The connection between the controller and the monitor can be made using a cable up to 20 feet in length.

ALARM DELAY INFORMATION

For some Automated Impella® Controller alarms, there is a short delay between the triggered event and the audible annunciation and visual display of the alarm.

Impella Defective	8 second delay
Impella Position Wrong	11±5 second delay
Controller Error	12±3 second delay
Emergency Shutdown Imminent	15±1 second delay
Battery Failure	28±8 second delay
Controller Failure	38±8 second delay
Battery Comm. Failure	40±10 second delay
Purge System Blocked	75±45 second delay

PATIENT ENVIRONMENT

The Automated Impella® Controller and the components of the Impella® System are approved for use within the patient environment defined in IEC 60601-1: 3rd edition and in the figure below.

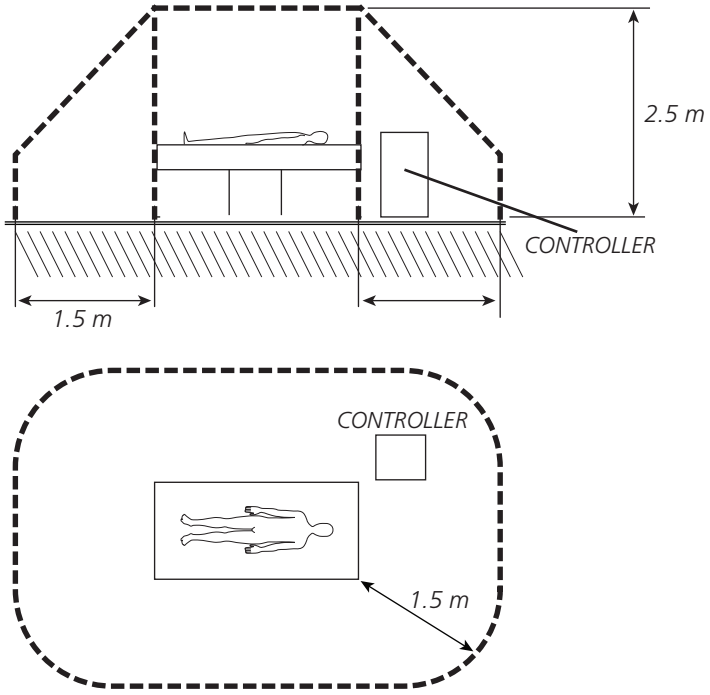


Figure 8.1 Automated Impella® Controller Patient Environment

WHITE CONNECTOR CABLE

Length	2.5 m
Service life	Single use only

IMPELLA® CATHETER PARAMETERS

Speed range	0 to 46,000 rpm
Power consumption	24 W
Voltage	Max. 20 V DC
Mean flow	3.3 L/min
Purging the Impella® Catheter	
Recommended purge fluid	20% dextrose solution with heparin concentration of 50 IU per mL
Dextrose concentration	5% to 40%
Purge pressure	300 to 1100 mmHg
Infusion rate	2 to 30 mL/h
Maximum duration of use	
US	6 hours
Catheter dimensions	
Length of invasive portion (without catheter)	130 ± 3 mm
Diameter	Max. 4.9 mm (nom. 4.7 mm)
Classification per DIN EN 60601-1 European Directive 93/42/EEC	Protection class II, degree of protection: CF (Automated Impella® Controller and Impella® Catheter)
Classification per MDD/93/42/EEC	Class III
Latex free	Yes

Latex Free

The Automated Impella® Controller and Impella® Catheter, including all accessories, are latex free.

IMPELLA CP® CATHETER DIMENSIONS

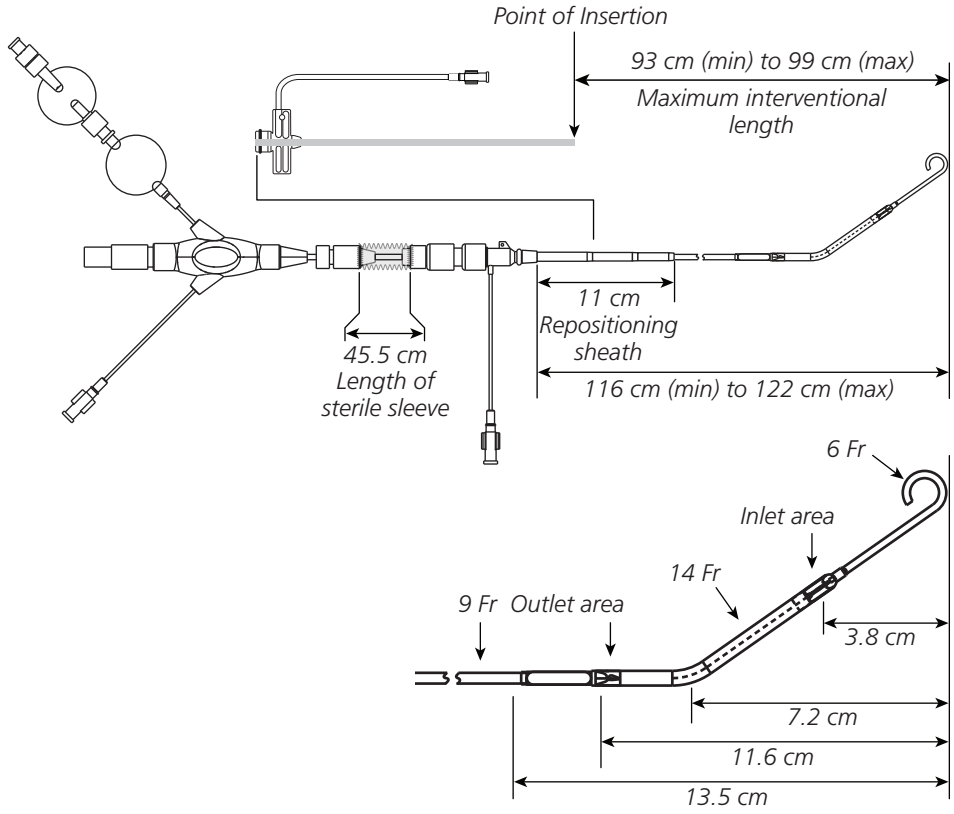


Figure 8.2 Impella CP® Catheter Dimensions

ANATOMIC CONSIDERATIONS

In a small number of cases (about 2 in every 100 patients) the Impella® Catheter cannot be successfully placed; or can be placed and the performance is compromised due to patients having anatomic conditions outside of the range for which the Impella® Catheter was designed.

The following table describes anatomic conditions that may affect the insertion or operation of the Impella® Catheter. Physicians should consider these characteristics when evaluating small or very tall patients for Impella® Catheter support.

Condition	Effect
The size and tortuosity of the femoral and iliac arteries	Limits the ability of the Impella® Catheter to be advanced from the insertion site into the left ventricle
Distance from the insertion site to the apex of the left ventricle	For very tall patients, the maximum interventional length may not be sufficient to allow correct placement of the Impella® Catheter
Systolic left ventricular (LV) long axis < 7 cm	The Impella® Catheter may interfere with the mitral valve
Systolic left ventricular (LV) long axis > 11 cm	The Impella® Catheter pigtail will not have a surface to push against to help stabilize its position, and may have a tendency to swing or bounce

CLEANING

- Clean the Automated Impella® Controller keypad and display with either 70% isopropyl alcohol or soap and water. (NOTE: Be aware that soft buttons may be activated when you spray or wipe the display.)
- Clean the Automated Impella® Controller housing with mild detergent.
- Do NOT clean with or expose any part of the clear sidearm of the Impella® Catheter (eg, infusion filter, pressure reservoir) to alcohol. Alcohol has been shown to cause cracks and leaks in these components. Carefully read labels on common skin preps and lotions to avoid using any alcohol-containing products in the area of the infusion filter or pressure reservoir.
- Do NOT allow any fluids to enter the connector sockets.
- Clean the connector cable with 70% isopropyl alcohol.

Alcohol Warning

Do NOT clean the Impella® Catheter infusion filter or pressure reservoir with alcohol and AVOID exposing these components to products containing alcohol.

STORING THE AUTOMATED IMPELLA® CONTROLLER

Storing the Controller

To keep the Automated Impella® Controller battery charged, the controller should be plugged into an AC outlet. When plugged into an AC outlet, the controller battery will charge whether the controller is on or off.

The Li-Ion batteries must be charged for 5 hours prior to system operation in order to meet the runtime requirement of 1 hour. Failure to do so will yield a shorter runtime. After being unplugged, the Automated Impella® Controller will operate for at least 60 minutes after the batteries have been fully charged.

- Place the Automated Impella® Controller on a horizontal surface to prevent falling.
- Connect the AC power cord to an AC outlet.
- The battery may be destroyed if the Automated Impella® Controller is stored with a depleted battery.

RETURNING AN IMPELLA® CATHETER TO ABIOMED (UNITED STATES)

To return an Impella® Catheter to Abiomed, contact your local Clinical Consultant for an Abiomed-approved return kit.* The kit includes instructions for returning the Impella® Catheter to Abiomed.

** Only available in the United States*

APPENDICES

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APPENDIX B: ABIOMED-APPROVED INTRODUCERS B.1

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APPENDIX A: IMPELLA® SYSTEM LIMITED SERVICE WARRANTY (UNITED STATES)

Abiomed®, Inc. warrants that, at the time of installation, all Impella® Systems (the "Goods") sold will be free from defects in material and workmanship and remain free from defects under normal use and service for a period of one (1) year from the date of shipment. Extended warranty and service may, at Abiomed's option, be offered for an additional charge, in which event separate or additional terms and conditions may apply. This warranty provides coverage for the Automated Impella® Controller.

This warranty does not cover routine preventative maintenance or replacement parts that are consumed per the controller's periodic maintenance schedule outlined in the Operator's and Service Manuals.

The express warranty set forth on this page is the only warranty given by Abiomed with respect to any goods furnished hereunder. Abiomed makes no other warranty, express, implied or arising by custom or trade usage, and specifically makes no warranty of merchantability or of fitness for any particular purpose. Said express warranty shall not be enlarged or otherwise affected by Abiomed's rendering of technical or other advice or service in connection with the Goods.

Abiomed shall not be liable for incidental or consequential losses, damages or expenses, directly or indirectly arising from the sale, handling or use of the Goods, or from any other cause relating thereto, and Abiomed's sole responsibility under this warranty will be, at its option, to 1) repair or replace the Goods or any components of the Goods found to be defective in workmanship or material during the foregoing warranty period, or 2) to refund the purchase price paid. All replaced components and Goods will become the property of Abiomed. This warranty shall not apply if the Goods have been: (a) repaired or altered in any way by other than Abiomed or Abiomed authorized service personnel; (b) subjected to physical or electrical abuse or misuse; or (c) operated in a manner inconsistent with Abiomed's instructions for use of the Goods. If Abiomed determines that a claim was not caused by Abiomed or Abiomed's authorized service personnel, then Buyer shall pay Abiomed for all related costs incurred by Abiomed. This warranty is not transferable without the express written consent of Abiomed.

Under this warranty, Abiomed will provide at no charge, updates or modifications which directly affect the safe operation of the Goods. Abiomed is not obligated to provide updates or modifications which provide (a) product improvement or enhancement; (b) new product features, or (c) options to the Goods.

Abiomed has no obligation to provide a loaner system during service or maintenance of the Goods. However, at Abiomed's sole discretion, Abiomed may provide such loaner systems.

This warranty applies to the Automated Impella® Controller and not to any disposable or other component of the Impella® System. Specific items excluded from this warranty include, but are not limited to, pumps, external tubing, and accessories.

This warranty may not be amended without the express written consent of an authorized officer of Abiomed.

APPENDIX B: ABIOMED-APPROVED INTRODUCERS

Abiomed has developed and qualified an introducer kit for use with the Impella Catheter. This kit was specifically designed for use with the Impella® Catheter and takes into account several technical parameters, such as:

- Size of the sheath (internal diameter and length)
- Blood leakage through the hemostatic valve
- Force required to pass the device through the hemostatic valve
- The ability to replace the introducer with a longer-term sheath

Testing and qualification, based on the above criteria, has been completed.

Table B.1 describes alternative introducer sheaths that have been tested and approved for use with the Impella® System. Use this information to evaluate the performance of these alternative introducer sheaths relative to each other and to the Abiomed-provided introducer.

Table B.1 Alternative Introducer Sheaths

Manufacture	Model	Fr	Length	Catalog Number
Cook Incorporated	Check-Flo Performer® Introducer *(non peel-away)*	14	30 cm	RCFW-14.0-38-30-J

Note: Use of the Cook introducer may require higher than expected insertion and removal forces.

APPENDIX C: AUTOMATED IMPELLA® CONTROLLER MENU STRUCTURE

OVERVIEW

The soft buttons on the Automated Impella® Controller provide access to the controller menu structure. The menu structure has 5 main elements:

- **MUTE ALARM**
- **FLOW CONTROL**
- **DISPLAY**
- **PURGE SYSTEM**
- **MENU**

This Appendix provides an overview of the Automated Impella® Controller menu structure. Many of the functions accessed through this menu structure are also discussed elsewhere in this manual.

MUTE ALARM

The **MUTE ALARM** soft button mutes (silences) active alarms. It does not open another menu.

When you press **MUTE ALARM**, a bell icon with an X through it replaces the words "MUTE ALARM" in the upper right of the display screen. If no alarms are active, no bell icon is displayed. When you press **MUTE ALARM** it acknowledges all active alarms and silences the audible alarm indicator for 2 minutes (for red or yellow alarms) or 5 minutes (for white alarms). (Refer to section 7 of this manual for more information about Automated Impella® Controller alarms.)

FLOW CONTROL

The **FLOW CONTROL** soft button opens the **FLOW CONTROL** menus. Before the Impella® Catheter is started, the menu options include **OFF** and **Start Pump**. Once the controller is running, the menu options include **BOOST, AUTO**, and P-levels between P-0 and P-8 as shown in Figure 5.24 in this manual. The procedure for setting P-level is described in "Positioning and Starting the Impella® Catheter" in section 5.

DISPLAY

The **DISPLAY** soft button opens a menu that includes the following options for viewing waveforms and navigating to other screen displays:

- **Y-axis Scale** – opens a menu from which you can select a waveform and change its appearance by adjusting the scale of the y-axis.

  Once the waveform is selected, turn the selector knob clockwise to increase the y-axis scale and counterclockwise to decrease the y-axis scale.

  Select **OK** to accept the new y-axis scale.

  Select **Restore Default** to return to the default y-axis scale.

  Select **Center Signal** to center the waveform.

  Select **Cancel** to exit the tool.

- **Time Scale** – allows you to apply different time scales to the currently displayed waveforms.
- **Center Motor Current** – automatically centers the motor current waveform and adjusts the range accordingly.
- **Infusion** – opens the Infusion History screen. The Infusion History screen, which is discussed in section 4 of this manual, shows the volume and amount of heparin and dextrose delivered. The top entry in the table shows the volume and amount of heparin and dextrose infused from the top of the hour through the current time.
- **Purge** – displays the purge system waveforms and pressure and flow values.
- **Placement** – opens the placement signal / motor current placement screen (described in section 4 under "Placement Screen").
- **Home** – opens the home screen (described in section 4 under "Home Screen").

PURGE SYSTEM

The **PURGE SYSTEM** soft button opens a menu that includes the following purge system procedure options:

- **Change Purge Fluid** – starts the procedure to change the purge fluid
- **Change Purge Cassette** – starts the procedure to replace the purge cassette
- **Change Purge System** – starts the procedure to change both the purge fluid and purge cassette
- **De-air Purge System** – starts the de-air procedure
- **Transfer to Standard Configuration** – starts the procedure for transferring from the set-up configuration of the Impella® System to the standard configuration.

These procedures are described in section 5 of this manual.

MENU

The **MENU** soft button opens a menu of options related to controller settings, alarm history, and starting a procedure. The menu includes the following options:

- **Settings / Service**

  Service

  System Information. Opens the System Information table. This provides information about the software version, IP addresses, current type of Impella® Catheter, and current catheter runtime.

  Set Date/Time. Displays the menu for changing the date and time

  Service Timers. Displays the Service Timers menu. Controller operating time and purge motor operating time are displayed in hours.

  Screen Brightness. Opens the Screen Brightness selection box. The brightness of the screen display can be set from 50% to 100%.

  Language. Opens the Language selection box. Use the selector knob to select German, English, French, Italian, Spanish, or Dutch. The system will immediately change the language on the controller for all displayed text. This language will be used after system restart unless another language is selected.

  Log Export. Displays the Log Export menu for exporting all logs to a USB stick.

  Disable (Enable) Placement Monitoring.

  Disable (Enable) Reverse Flow Control.

  Disable (Enable) Audio – Impella Sensor Failure. Allows you to enable or disable audio for the Impella Sensor Failure alarm. This selection is available only if an Impella Sensor Failure alarm is active or the audio has been disabled for this alarm.

  Disable (Enable) Audio – Purge Flow Low/System Blocked. Allows you to enable or disable audio for the Purge Flow Low or Purge System Blocked alarms. This selection is only available if one of these two alarms is active or the audio has been disabled for one of these alarms.

- **Alarm History** – opens the Alarm History table. This provides a visual display of the chronology of stored alarm messages. The most recently occurring alarm message is displayed at the top of the list. For each message, the date and time it occurred and the alarm message heading is displayed. You can use the selector knob to select individual alarm messages and an explanation for the selected alarm message will be displayed in the failure description box.
- **Start Data Snapshot** – starts the timed data recording function to save real-time operating data for later analysis. Timed Data Recording is described under "Timed Data Recording" in section 6 of this manual.
- **Case Start** – begins the case procedure. Case Start is described in section 5 of this manual under "Case Start."

APPENDIX D: AXILLARY INSERTION TECHNIQUE

The Impella Catheter can be inserted surgically through the axillary artery if factors such as scarring or tortuous or diseased vessels preclude femoral insertion. This appendix provides an overview of the surgical technique for axillary insertion of the Impella® Catheter.

SUPPLIES NEEDED

In addition to the supplies used for femoral artery insertion of the Impella® Catheter, you will also need the following for axillary insertion:

- 8 or 10 mm x 20 cm vascular graft
- 6 or 8 Fr sheath

OVERVIEW OF SURGICAL TECHNIQUE FOR AXILLARY INSERTION

1. Expose the axillary artery and wrap vessel loops distal and proximal to the point of incision.
2. Make an incision between the loops and attach an 8 or 10 mm vascular graft.
3. Attach a standard 6 or 8 Fr sheath to the end of the graft to control bleeding.
4. Insert the diagnostic catheter over a diagnostic guidewire into the left ventricle.
5. Remove the diagnostic guidewire and exchange it for the supplied 0.018 inch placement guidewire.
6. Remove the 6 or 8 Fr sheath.
7. Backload the Impella Catheter over the guidewire and insert the catheter into the vessel, advancing it along the placement guidewire into the left ventricle.
8. Remove the guidewire.
9. Cut the graft and advance the repositioning sheath into the remaining end of the graft.
10. Secure the sheath and close the incision site.

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